

1201 Constitution Ave., NW  
Washington, DC 20004  
Phone: 202-564-9042, Fax: 202-564-9490

---

**From:** Berger, Tom C. <Berger@khlaw.com>  
**Sent:** Thursday, April 16, 2020 12:28 PM  
**To:** Bauer, Jeff <Bauer.Jeff@epa.gov>  
**Cc:** Daniels, Rhys G. <daniels@khlaw.com>; Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>  
**Subject:** RE: **Ex. 4 CBI**

Hi Jeff –

I hope that all is well.

Just checking in re status update. A non-CBI-containing email from you would probably be the best (if needed at some later time we can use EPA's new CBI via email authorization form if the submitter agrees).

Thanks again – Tom

---

**From:** Berger, Tom C.  
**Sent:** Wednesday, April 8, 2020 11:06 AM  
**To:** Bauer, Jeff <Bauer.Jeff@epa.gov>; Schweer, Greg <Schweer.Greg@epa.gov>  
**Cc:** Daniels, Rhys G. <daniels@khlaw.com>; Price, Amanda <price@khlaw.com>  
**Subject:** RE: **Ex. 4 CBI**

Jeff – thanks much for the update. Hope you and all at EPA are staying safe.

Tom

---

**From:** Bauer, Jeff <Bauer.Jeff@epa.gov>  
**Sent:** Wednesday, April 8, 2020 11:03 AM  
**To:** Berger, Tom C. <Berger@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>  
**Cc:** Daniels, Rhys G. <daniels@khlaw.com>; Price, Amanda <price@khlaw.com>  
**Subject:** RE: **Ex. 4 CBI**

Tom,

# Ex. 4 CBI

I will follow up with you next wed with a status update.

Jeff Bauer - Program Manager  
United States Environmental Protection Agency (USEPA)  
Office of Pollution Prevention and Toxics (OPPT)  
New Chemicals Program (7405M)  
<http://www.epa.gov/oppt/newchemicals/>

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Washington, DC 20004  
Phone: 202-564-9042, Fax: 202-564-9490

---

**From:** Berger, Tom C. <Berger@khlaw.com>  
**Sent:** Wednesday, April 08, 2020 10:48 AM  
**To:** Schweer, Greg <Schweer.Greg@epa.gov>  
**Cc:** Daniels, Rhys G. <daniels@khlaw.com>; Bauer, Jeff <Bauer.Jeff@epa.gov>; Price, Amanda <price@khlaw.com>  
**Subject:** RE: **Ex. 4 CBI**

Hi Greg –

I was just going through my to-do list and thought I would circle back on these two cases. I hope everyone is hanging in there.

Thanks again – Tom

---

**From:** Berger, Tom C.  
**Sent:** Monday, March 30, 2020 3:46 PM  
**To:** Schweer, Greg <Schweer.Greg@epa.gov>  
**Cc:** Daniels, Rhys G. <daniels@khlaw.com>; Bauer, Jeff <Bauer.Jeff@epa.gov>; Price, Amanda <price@khlaw.com>  
**Subject:** RE: **Ex. 4 CBI**

Greg / all – completely understood – thank you so much.

Tom

---

**From:** Schweer, Greg <Schweer.Greg@epa.gov>  
**Sent:** Monday, March 30, 2020 3:42 PM  
**To:** Berger, Tom C. <Berger@khlaw.com>  
**Cc:** Daniels, Rhys G. <daniels@khlaw.com>; Bauer, Jeff <Bauer.Jeff@epa.gov>  
**Subject:** RE: **Ex. 4 CBI**

Hi Tom.

I am not ignoring you. I did check with Jeff Bauer early last week on this case. He filled me in on the requests he had made of RAD to review submitted test data and your request for a meeting. However, believe it or not, we have been having issues reliably being able to access our CBI-secure LAN. This hampers our ability to efficiently complete work. I will check on the status of your case as soon as I can.

---

**From:** Berger, Tom C. <Berger@khlaw.com>  
**Sent:** Monday, March 30, 2020 11:51 AM  
**To:** Schweer, Greg <Schweer.Greg@epa.gov>  
**Cc:** Daniels, Rhys G. <daniels@khlaw.com>  
**Subject:** RE: **Ex. 4 CBI**

Hi Greg –

Hope all is well.

Just thought I would check in with you on the **Ex. 4 CBI** LVEA (Lauren Davis) and **Ex. 4 CBI** **Ex. 4 CBI** with Jeff Bauer.

Thanks all always - Tom

---

**From:** Berger, Tom C.  
**Sent:** Tuesday, March 24, 2020 11:12 AM  
**To:** Schweer, Greg <Schweer.Greg@epa.gov>  
**Cc:** Daniels, Rhys G. <daniels@khlaw.com>  
**Subject:** RE: **Ex. 4 CBI**

Greg – thanks so much as always. I also have an LVE with Lauren Davis **Ex. 4 CBI** **Ex. 4 CBI** held up in the process. Lauren has been responsive but the case has stalled (again, however, I understand the challenges you are facing).

These are my two “priority” cases.

Tom

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**From:** Schweer, Greg <Schweer.Greg@epa.gov>  
**Sent:** Tuesday, March 24, 2020 11:07 AM  
**To:** Berger, Tom C. <Berger@khlaw.com>  
**Cc:** Daniels, Rhys G. <daniels@khlaw.com>  
**Subject:** Re: **Ex. 4 CBI**

Tom,

Yes, things are a bit crazy. I will check into the case status today or tomorrow.

Sent from my iPhone

On Mar 24, 2020, at 10:48 AM, Berger, Tom C. <Berger@khlaw.com> wrote:

Hi Greg –

Obviously things are crazy and I don't want to push Jeff too hard but no response from Jeff on this case for a month.

Hang in there....

Tom

---

**From:** Berger, Tom C.  
**Sent:** Monday, March 23, 2020 6:22 PM  
**To:** Bauer, Jeff <Bauer.Jeff@epa.gov>  
**Cc:** Daniels, Rhys G. <daniels@khlaw.com>  
**Subject:** RE: **Ex. 4 CBI**

Hi Jeff –

Apologies – just want to make sure you are getting these emails. Understand if there are delays.

Tom

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**From:** Berger, Tom C.  
**Sent:** Thursday, March 19, 2020 5:22 PM  
**To:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>  
**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>  
**Subject:** RE: **Ex. 4 CBI**

Hi Jeff – checking in again – thanks - Tom

---

**From:** Berger, Tom C.  
**Sent:** Monday, March 16, 2020 1:40 PM  
**To:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>  
**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>  
**Subject:** RE: **Ex. 4 CBI**

Hi Jeff –

I know things are crazy but checking in again – thanks - Tom

---

**From:** Berger, Tom C.  
**Sent:** Wednesday, March 11, 2020 3:43 PM  
**To:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>  
**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>  
**Subject:** RE: **Ex. 4 CBI**

Hi Jeff –

Checking in again - thanks

---

**From:** Berger, Tom C.  
**Sent:** Friday, March 6, 2020 1:33 PM  
**To:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>  
**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>  
**Subject:** RE: **Ex. 4 CBI**

Hi Jeff –

The submitter is quite anxious – can we touch base next week?

Thanks much - Tom

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**From:** Berger, Tom C.  
**Sent:** Tuesday, February 25, 2020 9:08 AM  
**To:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>  
**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>  
**Subject:** RE: **Ex. 4 CBI**



Hi Jeff –

Just checking in on this – thanks - Tom

---

**From:** Berger, Tom C.  
**Sent:** Thursday, February 20, 2020 12:18 PM  
**To:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>  
**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>  
**Subject:** RE: **Ex. 4 CBI**

Hi Jeff –

I hope that all is well.

Per our discussions, the submitter has modified the questions to focus on toxicity/risk issues and submitted them via CDX yesterday. Can we start looking at conference call dates the week of March 9?

Thanks and best regards,  
Tom

Thomas C. Berger  
Partner  
tel: 202.434.4285 | fax: 202.434.4646 | [berger@khlaw.com](mailto:berger@khlaw.com)  
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**From:** Berger, Tom C.  
**Sent:** Wednesday, January 29, 2020 11:41 AM  
**To:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>  
**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>  
**Subject:** RE: **Ex. 4 CBI**

Hi Jeff –

Apologies we keep playing phone tag – can we discuss how to convert the below questions into questions that would be acceptable to RAD so we can schedule a call with you and RAD? Your voicemail suggested the below are more legal/regulatory than risk-based questions. We still need the below questions answered – perhaps we tee up the more scientific ones for RAD then have the call to address both types of questions. The submitter is under growing commercial pressure.

Thanks much again - Tom

---

**From:** Berger, Tom C.  
**Sent:** Monday, January 20, 2020 3:50 PM  
**To:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>  
**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>  
**Subject:** RE: **Ex. 4 CBI**

Hi Jeff –

Apologies that we could not connect last week. Let's try to touch base tomorrow (Tuesday) if possible to discuss how to move this forward.

Thanks again – Tom

Thomas C. Berger  
Partner  
tel: 202.434.4285 | fax: 202.434.4646 | [berger@khlaw.com](mailto:berger@khlaw.com)  
1001 G Street, N.W., Suite 500 West | Washington, D.C. 20001

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**From:** Berger, Tom C.  
**Sent:** Monday, January 13, 2020 2:50 PM  
**To:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>  
**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>  
**Subject:** RE: **Ex. 4 CBI**  
**Importance:** High

Hi Jeff –

Following is the list of questions we are considering submitting through CDX. Please let me know if these look ok.

Thanks again and best regards,  
Tom

\* \* \*

(1) Based on review of the submitted physical-chemical properties test data, does EPA now agree that use **Ex. 4 CBI** as described in the PMN poses no unreasonable risk of injury and so plans to revoke the consent order?

(2) If so, what is the process for revoking the current consent

*order? Does the submitter now need to request that EPA revoke the order, or will EPA itself initiate revocation? What is the expected timing for revocation? How would EPA communicate such revocation?*

*(3) How would revocation of the consent order impact the final SNUR for the subject substance?*

*(4) Would a SNUN be a more expedient approach?*

\* \* \*

---

**From:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>  
**Sent:** Wednesday, January 8, 2020 8:56 AM  
**To:** Berger, Tom C. <[Berger@khlaw.com](mailto:Berger@khlaw.com)>  
**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>  
**Subject:** RE: **Ex. 4 CBI**

Tom, I am expecting information from the engineer today or tomorrow on the **Ex. 4 CBI** test, I left you a message. There is a new procedure for us to set up meeting with RAD. I am to have the submitter send in a list of questions for RAD, they will assign someone up there as a Lead person who has two weeks and will set a date for when we can have a meeting. This may be our best route to other than just me bugging them to get things done. There were a series of emails on this case last week but now everyone is back from the holidays I am trying to get this case moving again.

Jeff Bauer - Program Manager  
United States Environmental Protection Agency (USEPA)  
Office of Pollution Prevention and Toxics (OPPT)  
New Chemicals Program (7405M)  
<http://www.epa.gov/oppt/newchems/>

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---

**From:** Berger, Tom C. <[Berger@khlaw.com](mailto:Berger@khlaw.com)>  
**Sent:** Tuesday, January 07, 2020 4:16 PM  
**To:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>  
**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>  
**Subject:** RE: **Ex. 4 CBI**

Hi Jeff –

I hope you had a great holiday! The client was wondering if we could have a conference call on this, this week or next. Please advise.

Thanks much – Tom

Thomas C. Berger  
Partner  
tel: 202.434.4285 | fax: 202.434.4646 | [berger@khlaw.com](mailto:berger@khlaw.com)  
1001 G Street, N.W., Suite 500 West | Washington, D.C. 20001

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**From:** Berger, Tom C.  
**Sent:** Tuesday, December 10, 2019 2:10 PM  
**To:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>  
**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>  
**Subject:** RE: **Ex. 4 CBI**

Hi Jeff –

Just checking back in – thanks - Tom

---

**From:** Berger, Tom C.  
**Sent:** Thursday, December 5, 2019 9:46 AM  
**To:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>  
**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>  
**Subject:** RE: **Ex. 4 CBI**

Hi Jeff –

When we spoke before Thanksgiving (I hope you had a great one!) you indicated that the reports were being reviewed and that I should reach out to you in early December.

Is there any update?

Thanks much and best regards – Tom

Thomas C. Berger  
Partner  
tel: 202.434.4285 | fax: 202.434.4646 | [berger@khlaw.com](mailto:berger@khlaw.com)  
1001 G Street, N.W., Suite 500 West | Washington, D.C. 20001

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**From:** Berger, Tom C.  
**Sent:** Monday, November 18, 2019 1:17 PM  
**To:** Bauer, Jeff <Bauer.Jeff@epa.gov>  
**Cc:** Daniels, Rhys G. <daniels@khlaw.com>  
**Subject:** RE: **Ex. 4 CBI**

Hi Jeff –

The PMN submitter asked me to reach out to you to see if we can schedule a conference call (including EPA, K&H, and the submitter) on this case re status and pathforward.

Thanks - Tom

---

**From:** Bauer, Jeff <Bauer.Jeff@epa.gov>  
**Sent:** Friday, March 29, 2019 5:43 PM  
**To:** Berger, Tom C. <Berger@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>  
**Cc:** Daniels, Rhys G. <daniels@khlaw.com>  
**Subject:** RE: **Ex. 4 CBI**

Tom,  
I set the meeting up for Wednesday April 3, at 11 am. RAD has accepted the invitation for that time.

Jeff Bauer - Program Manager  
United States Environmental Protection Agency (USEPA)  
Office of Pollution Prevention and Toxics (OPPT)  
New Chemicals Program (7405M)  
<http://www.epa.gov/oppt/newchems/>

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---

**From:** Bauer, Jeff  
**Sent:** Tuesday, March 26, 2019 11:37 AM  
**To:** 'Berger, Tom C.' <Berger@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>  
**Cc:** Daniels, Rhys G. <daniels@khlaw.com>  
**Subject:** RE: **Ex. 4 CBI**

Tom, I left you a voice message, I am seeing what time it best for RAD to be part of the call.

Jeff Bauer - Program Manager  
United States Environmental Protection Agency (USEPA)  
Office of Pollution Prevention and Toxics (OPPT)  
New Chemicals Program (7405M)  
<http://www.epa.gov/oppt/newchems/>

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Phone: 202-564-9042, Fax: 202-564-9490

---

**From:** Berger, Tom C. <Berger@khlaw.com>  
**Sent:** Tuesday, March 26, 2019 11:30 AM  
**To:** Bauer, Jeff <Bauer.Jeff@epa.gov>; Schweer, Greg <Schweer.Greg@epa.gov>  
**Cc:** Daniels, Rhys G. <daniels@khlaw.com>  
**Subject:** RE: **Ex. 4 CBI**

Hi folks –

Just thought I would check in with you on this.

Thanks again - Tom

---

**From:** Berger, Tom C.  
**Sent:** Friday, March 22, 2019 2:12 PM  
**To:** 'Bauer.jeff@Epa.gov' <Bauer.jeff@Epa.gov>; 'Schweer, Greg' <Schweer.Greg@epa.gov>  
**Cc:** Daniels, Rhys G. <daniels@khlaw.com>  
**Subject:** **Ex. 4 CBI**

Hi folks –

I hope you are doing well. Jeff – this is the PMN case that my colleague, Dr. Rhys Daniels, spoke with you about earlier this week.

The issue is development of data needed to amend the existing section 5(e) order for this substance to add an additional use, and EPA approval of protocols for same. Would the Agency be available for a short conference call on this on one of the following days?:

- March 27 (except 12-2 ET)
- April 2
- April 3
- April 4

This is becoming more urgent from a commercial standpoint.

Thanks much - Tom

Thomas C. Berger  
Partner  
tel: 202.434.4285 | fax: 202.434.4646 | [berger@khlaw.com](mailto:berger@khlaw.com)  
1001 G Street, N.W., Suite 500 West | Washington, D.C. 20001

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Message

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**From:** Berger, Tom C. [Berger@khlaw.com]  
**Sent:** 5/7/2020 8:16:30 PM  
**To:** Bauer, Jeff [Bauer.Jeff@epa.gov]  
**CC:** Price, Amanda [price@khlaw.com]; Schweer, Greg [Schweer.Greg@epa.gov]; Daniels, Rhys G. [daniels@khlaw.com]  
**Subject:** Re: **Ex. 4 CBI**

Jeff - thanks much.

Tom

On May 7, 2020, at 4:03 PM, Bauer, Jeff <Bauer.Jeff@epa.gov> wrote:

Tom, I hope you hanging in there as well, I have an email out to see if I can get a status update on the Assessor and to address you questions sent into CDX for a meeting.

Jeff

Jeff Bauer - Program Manager  
United States Environmental Protection Agency (USEPA)  
Office of Pollution Prevention and Toxics (OPPT)  
New Chemicals Program (7405M)  
<http://www.epa.gov/oppt/newchems/>

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Phone: 202-564-9042, Fax: 202-564-9490

---

**From:** Berger, Tom C. <Berger@khlaw.com>  
**Sent:** Thursday, May 07, 2020 1:57 PM  
**To:** Bauer, Jeff <Bauer.Jeff@epa.gov>  
**Cc:** Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>  
**Subject:** RE: **Ex. 4 CBI**

Hi Jeff – Just touching base as the submitter has requested a status update.

Thanks again - Tom

---

**From:** Berger, Tom C.  
**Sent:** Tuesday, May 5, 2020 11:56 AM  
**To:** 'Bauer, Jeff' <Bauer.Jeff@epa.gov>  
**Cc:** Price, Amanda <price@khlaw.com>; 'Schweer, Greg' <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>  
**Subject:** RE: **Ex. 4 CBI**

Hi Jeff – Just checking in on this – thanks - Tom



---

**From:** Berger, Tom C.  
**Sent:** Wednesday, April 29, 2020 11:12 AM  
**To:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>  
**Cc:** Price, Amanda <[price@khlaw.com](mailto:price@khlaw.com)>; Schweer, Greg <[Schweer.Greg@epa.gov](mailto:Schweer.Greg@epa.gov)>; Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>  
**Subject:** RE: **Ex. 4 CBI**

Hi Jeff –

I just thought I would check in on this and see if the Agency needs any additional information.

Thanks again and best regards,  
Tom

Thomas C. Berger  
Partner  
tel: 202.434.4285 | fax: 202.434.4646 | [berger@khlaw.com](mailto:berger@khlaw.com)  
1001 G Street, N.W., Suite 500 West | Washington, D.C. 20001

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**From:** Berger, Tom C.  
**Sent:** Thursday, April 23, 2020 7:13 PM  
**To:** 'Bauer, Jeff' <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>  
**Cc:** Price, Amanda <[price@khlaw.com](mailto:price@khlaw.com)>; Schweer, Greg <[Schweer.Greg@epa.gov](mailto:Schweer.Greg@epa.gov)>; Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>  
**Subject:** RE: **Ex. 4 CBI**

Jeff - thanks much.

Your recent voicemail and follow-up email indicated that the EPA Chemist has evaluated the study" on **Ex. 4 CBI** but that the reviewer did have a few questions and comments: **Ex. 4 CBI**

**Ex. 4 CBI**

# Ex. 4 CBI

To specifically answer the Chemist's questions:

# Ex. 4 CBI

# Ex. 4 CBI

\* \* \*

We trust that you find this information useful in resolved all outstanding issues. As always, if you have any questions please do not hesitate to contact us.

Best regards,  
Tom

Thomas C. Berger  
Partner  
tel: 202.434.4285 | fax: 202.434.4646 | [berger@khlaw.com](mailto:berger@khlaw.com)  
1001 G Street, N.W., Suite 500 West | Washington, D.C. 20001

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---

**From:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>  
**Sent:** Tuesday, April 21, 2020 5:17 PM  
**To:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>; Berger, Tom C. <[Berger@khlaw.com](mailto:Berger@khlaw.com)>  
**Cc:** Price, Amanda <[price@khlaw.com](mailto:price@khlaw.com)>; Schweer, Greg <[Schweer.Greg@epa.gov](mailto:Schweer.Greg@epa.gov)>  
**Subject:** RE: Ex. 4 CBI

I am moving forward with the review based on the information I have on the two studies, I wanted to share with you her comments on the test. Ex. 4 CBI

Ex. 4 CBI RAD has the information and I am trying to get them to do the risk assessment based on Ex. 4 CBI

Jeff Bauer - Program Manager  
United States Environmental Protection Agency (USEPA)  
Office of Pollution Prevention and Toxics (OPPT)  
New Chemicals Program (7405M)  
<http://www.epa.gov/oppt/newchemicals/>

EPA East Building, room 4133M  
1201 Constitution Ave., NW  
Washington, DC 20004  
Phone: 202-564-9042, Fax: 202-564-9490

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**From:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>  
**Sent:** Tuesday, April 21, 2020 4:58 PM  
**To:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>; Berger, Tom C. <[Berger@khlaw.com](mailto:Berger@khlaw.com)>  
**Cc:** Price, Amanda <[price@khlaw.com](mailto:price@khlaw.com)>; Schweer, Greg <[Schweer.Greg@epa.gov](mailto:Schweer.Greg@epa.gov)>  
**Subject:** RE: Ex. 4 CBI

Jeff,

As always, we hope that all is well.

Per your recent voicemail and follow-up email concerning the Ex. 4 CBI case, we understand that the chemist has two questions concerning Ex. 4 CBI

**Ex. 4 CBI**

Thanks in advance for your response.

Rhys G. Daniels, Ph.D.  
Staff Scientist  
tel: +1 202.434.4270 | fax: +1 202.434.4646 | [daniels@khlaw.com](mailto:daniels@khlaw.com)

1001 G Street NW, Suite 500 West | Washington, DC 20001

**From:** Bauer, Jeff <Bauer.Jeff@epa.gov>  
**Sent:** Thursday, April 16, 2020 1:02 PM  
**To:** Berger, Tom C. <Berger@khlaw.com>  
**Cc:** Daniels, Rhys G. <daniels@khlaw.com>; Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>  
**Subject:** RE: **Ex. 4 CBI**

Tom,

The chemist sent me a memo on the **Ex. 4 CBI** test and they had two questions, I called and left you a message today **Ex. 4 CBI** I sent RAD a request last week to update the HH assessment **Ex. 4 CBI** as in my April 4, 2020 email to you. I have two emails into RAD on this case and will try an update you again in a week or so. I requested RAD set up a date with me to have a meeting to discuss how to proceed with this PMN.

Thanks  
Jeff

Jeff Bauer - Program Manager  
United States Environmental Protection Agency (USEPA)  
Office of Pollution Prevention and Toxics (OPPT)  
New Chemicals Program (7405M)  
<http://www.epa.gov/oppt/newchems/>

EPA East Building, room 4133M  
1201 Constitution Ave., NW  
Washington, DC 20004  
Phone: 202-564-9042, Fax: 202-564-9490

**From:** Berger, Tom C. <Berger@khlaw.com>  
**Sent:** Thursday, April 16, 2020 12:28 PM  
**To:** Bauer, Jeff <Bauer.Jeff@epa.gov>  
**Cc:** Daniels, Rhys G. <daniels@khlaw.com>; Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>  
**Subject:** RE: **Ex. 4 CBI**

Hi Jeff –

I hope that all is well.

Just checking in re status update. A non-CBI-containing email from you would probably be the best (if needed at some later time we can use EPA's new CBI via email authorization form if the submitter agrees).

Thanks again – Tom

---

**From:** Berger, Tom C.  
**Sent:** Wednesday, April 8, 2020 11:06 AM  
**To:** Bauer, Jeff <Bauer.Jeff@epa.gov>; Schweer, Greg <Schweer.Greg@epa.gov>  
**Cc:** Daniels, Rhys G. <daniels@khlaw.com>; Price, Amanda <price@khlaw.com>  
**Subject:** RE: **Ex. 4 CBI**

Jeff – thanks much for the update. Hope you and all at EPA are staying safe.

Tom

---

**From:** Bauer, Jeff <Bauer.Jeff@epa.gov>  
**Sent:** Wednesday, April 8, 2020 11:03 AM  
**To:** Berger, Tom C. <Berger@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>  
**Cc:** Daniels, Rhys G. <daniels@khlaw.com>; Price, Amanda <price@khlaw.com>  
**Subject:** RE: **Ex. 4 CBI**

Tom,

# Ex. 4 CBI

I will follow up with you next wed with a status update.

Jeff Bauer - Program Manager  
United States Environmental Protection Agency (USEPA)  
Office of Pollution Prevention and Toxics (OPPT)  
New Chemicals Program (7405M)  
<http://www.epa.gov/oppt/newchems/>

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Washington, DC 20004  
Phone: 202-564-9042, Fax: 202-564-9490

---

**From:** Berger, Tom C. <Berger@khlaw.com>  
**Sent:** Wednesday, April 08, 2020 10:48 AM  
**To:** Schweer, Greg <Schweer.Greg@epa.gov>  
**Cc:** Daniels, Rhys G. <daniels@khlaw.com>; Bauer, Jeff <Bauer.Jeff@epa.gov>; Price, Amanda <price@khlaw.com>  
**Subject:** RE: **Ex. 4 CBI**

Hi Greg –

I was just going through my to-do list and thought I would circle back on these two cases. I hope everyone is hanging in there.

Thanks again – Tom

---

**From:** Berger, Tom C.  
**Sent:** Monday, March 30, 2020 3:46 PM  
**To:** Schweer, Greg <Schweer.Greg@epa.gov>  
**Cc:** Daniels, Rhys G. <daniels@khilaw.com>; Bauer, Jeff <Bauer.Jeff@epa.gov>; Price, Amanda <price@khilaw.com>  
**Subject:** RE: Ex. 4 CBI

Greg / all – completely understood – thank you so much.

Tom

---

**From:** Schweer, Greg <Schweer.Greg@epa.gov>  
**Sent:** Monday, March 30, 2020 3:42 PM  
**To:** Berger, Tom C. <Berger@khilaw.com>  
**Cc:** Daniels, Rhys G. <daniels@khilaw.com>; Bauer, Jeff <Bauer.Jeff@epa.gov>  
**Subject:** RE: Ex. 4 CBI

Hi Tom.

I am not ignoring you. I did check with Jeff Bauer early last week on this case. He filled me in on the requests he had made of RAD to review submitted test data and your request for a meeting. However, believe it or not, we have been having issues reliably being able to access our CBI-secure LAN. This hampers our ability to efficiently complete work. I will check on the status of your case as soon as I can.

---

**From:** Berger, Tom C. <Berger@khilaw.com>  
**Sent:** Monday, March 30, 2020 11:51 AM  
**To:** Schweer, Greg <Schweer.Greg@epa.gov>  
**Cc:** Daniels, Rhys G. <daniels@khilaw.com>  
**Subject:** RE: Ex. 4 CBI

Hi Greg –

Hope all is well.

Just thought I would check in with you on the Ex. 4 CBI LVEA (Lauren Davis) and Ex. 4 CBI with Jeff Bauer.

Thanks all always - Tom

---

**From:** Berger, Tom C.  
**Sent:** Tuesday, March 24, 2020 11:12 AM  
**To:** Schweer, Greg <Schweer.Greg@epa.gov>  
**Cc:** Daniels, Rhys G. <daniels@khilaw.com>  
**Subject:** RE: Ex. 4 CBI

Greg – thanks so much as always. I also have an LVE with Lauren Davis

**Ex. 4 CBI**

**Ex. 4 CBI** held up in the process. Lauren has been responsive but the case has stalled (again, however, I understand the challenges you are facing).

These are my two “priority” cases.

Tom

---

**From:** Schweer, Greg <Schweer.Greg@epa.gov>

**Sent:** Tuesday, March 24, 2020 11:07 AM

**To:** Berger, Tom C. <Berger@khlaw.com>

**Cc:** Daniels, Rhys G. <daniels@khlaw.com>

**Subject:** Re: **Ex. 4 CBI**

Tom,

Yes, things are a bit crazy. I will check into the case status today or tomorrow.

Sent from my iPhone

On Mar 24, 2020, at 10:48 AM, Berger, Tom C. <Berger@khlaw.com> wrote:

Hi Greg –

Obviously things are crazy and I don’t want to push Jeff too hard but no response from Jeff on this case for a month.

Hang in there....

Tom

---

**From:** Berger, Tom C.

**Sent:** Monday, March 23, 2020 6:22 PM

**To:** Bauer, Jeff <Bauer.Jeff@epa.gov>

**Cc:** Daniels, Rhys G. <daniels@khlaw.com>

**Subject:** RE: **Ex. 4 CBI**

Hi Jeff –

Apologies – just want to make sure you are getting these emails. Understand if there are delays.

Tom

---

**From:** Berger, Tom C.

**Sent:** Thursday, March 19, 2020 5:22 PM

**To:** Bauer, Jeff <Bauer.Jeff@epa.gov>

**Cc:** Daniels, Rhys G. <daniels@khlaw.com>

**Subject:** RE: **Ex. 4 CBI**

Hi Jeff – checking in again – thanks - Tom



---

**From:** Berger, Tom C.  
**Sent:** Monday, March 16, 2020 1:40 PM  
**To:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>  
**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>  
**Subject:** RE: **Ex. 4 CBI**

Hi Jeff –

I know things are crazy but checking in again – thanks - Tom

---

**From:** Berger, Tom C.  
**Sent:** Wednesday, March 11, 2020 3:43 PM  
**To:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>  
**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>  
**Subject:** RE: **Ex. 4 CBI**

Hi Jeff –

Checking in again - thanks

---

**From:** Berger, Tom C.  
**Sent:** Friday, March 6, 2020 1:33 PM  
**To:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>  
**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>  
**Subject:** RE: **Ex. 4 CBI**

Hi Jeff –

The submitter is quite anxious – can we touch base next week?

Thanks much - Tom

---

**From:** Berger, Tom C.  
**Sent:** Tuesday, February 25, 2020 9:08 AM  
**To:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>  
**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>  
**Subject:** RE: **Ex. 4 CBI**

Hi Jeff –

Just checking in on this – thanks - Tom

---

**From:** Berger, Tom C.  
**Sent:** Thursday, February 20, 2020 12:18 PM  
**To:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>  
**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>  
**Subject:** RE: **Ex. 4 CBI**

Hi Jeff –

I hope that all is well.

Per our discussions, the submitter has modified the questions to focus on toxicity/risk issues and submitted them via CDX yesterday. Can we start looking at conference call dates the week of March 9?

Thanks and best regards,  
Tom

Thomas C. Berger  
Partner  
tel: 202.434.4285 | fax: 202.434.4646 | [berger@khlaw.com](mailto:berger@khlaw.com)  
1001 G Street, N.W., Suite 500 West | Washington, D.C. 20001

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**From:** Berger, Tom C.  
**Sent:** Wednesday, January 29, 2020 11:41 AM  
**To:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>  
**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>  
**Subject:** RE: **Ex. 4 CBI**

Hi Jeff –

Apologies we keep playing phone tag – can we discuss how to convert the below questions into questions that would be acceptable to RAD so we can schedule a call with you and RAD? Your voicemail suggested the below are more legal/regulatory than risk-based questions. We still need the below questions answered – perhaps we tee up the more scientific ones for RAD then have the call to address both types of questions. The submitter is under growing commercial pressure.

Thanks much again - Tom

---

**From:** Berger, Tom C.  
**Sent:** Monday, January 20, 2020 3:50 PM  
**To:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>  
**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>  
**Subject:** RE: **Ex. 4 CBI**

Hi Jeff –

Apologies that we could not connect last week. Let's try to touch base tomorrow (Tuesday) if possible to discuss how to move this forward.

Thanks again – Tom

Thomas C. Berger  
Partner  
tel: 202.434.4285 | fax: 202.434.4646 | [berger@khlaw.com](mailto:berger@khlaw.com)  
1001 G Street, N.W., Suite 500 West | Washington, D.C. 20001

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**From:** Berger, Tom C.  
**Sent:** Monday, January 13, 2020 2:50 PM  
**To:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>  
**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>  
**Subject:** RE: **Ex. 4 CBI**  
**Importance:** High

Hi Jeff –

Following is the list of questions we are considering submitting through CDX. Please let me know if these look ok.

Thanks again and best regards,  
Tom

\* \* \*

*(1) Based on review of the submitted physical-chemical properties test data, does EPA now agree that use **Ex. 4 CBI** as described in the PMN poses no unreasonable risk of injury and so plans to revoke the consent order?*

*(2) If so, what is the process for revoking the current consent order? Does the submitter now need to request that EPA revoke the order, or will EPA itself initiate revocation? What is the expected timing for revocation? How would EPA communicate such revocation?*

*(3) How would revocation of the consent order impact the final SNUR for the subject substance?*

*(4) Would a SNUN be a more expedient approach?*

\* \* \*

---

**From:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>  
**Sent:** Wednesday, January 8, 2020 8:56 AM  
**To:** Berger, Tom C. <[Berger@khlaw.com](mailto:Berger@khlaw.com)>

**Cc:** Daniels, Rhys G. <daniels@khlaw.com>

**Subject:** RE: **Ex. 4 CBI**

Tom, I am expecting information from the engineer today or tomorrow on the **Ex. 4 CBI** test. I left you a message. There is a new procedure for us to set up meeting with RAD. I am to have the submitter send in a list of questions for RAD, they will assign someone up there as a Lead person who has two weeks and will set a date for when we can have a meeting. This may be our best route to other than just me bugging them to get things done. There were a series of emails on this case last week but now everyone is back from the holidays I am trying to get this case moving again.

Jeff Bauer - Program Manager  
United States Environmental Protection Agency (USEPA)  
Office of Pollution Prevention and Toxics (OPPT)  
New Chemicals Program (7405M)  
<http://www.epa.gov/oppt/newchemicals/>

EPA East Building, room 4133M  
1201 Constitution Ave., NW  
Washington, DC 20004  
Phone: 202-564-9042, Fax: 202-564-9490

---

**From:** Berger, Tom C. <Berger@khlaw.com>

**Sent:** Tuesday, January 07, 2020 4:16 PM

**To:** Bauer, Jeff <Bauer.Jeff@epa.gov>

**Cc:** Daniels, Rhys G. <daniels@khlaw.com>

**Subject:** RE: **Ex. 4 CBI**

Hi Jeff –

I hope you had a great holiday! The client was wondering if we could have a conference call on this, this week or next. Please advise.

Thanks much – Tom

Thomas C. Berger  
Partner  
tel: 202.434.4285 | fax: 202.434.4646 | [berger@khlaw.com](mailto:berger@khlaw.com)  
1001 G Street, N.W., Suite 500 West | Washington, D.C. 20001

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**From:** Berger, Tom C.  
**Sent:** Tuesday, December 10, 2019 2:10 PM  
**To:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>  
**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>  
**Subject:** RE: **Ex. 4 CBI**

Hi Jeff –

Just checking back in – thanks - Tom

---

**From:** Berger, Tom C.  
**Sent:** Thursday, December 5, 2019 9:46 AM  
**To:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>  
**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>  
**Subject:** RE: **Ex. 4 CBI**

Hi Jeff –

When we spoke before Thanksgiving (I hope you had a great one!) you indicated that the reports were being reviewed and that I should reach out to you in early December.

Is there any update?

Thanks much and best regards – Tom

Thomas C. Berger  
Partner  
tel: 202.434.4285 | fax: 202.434.4646 | [berger@khlaw.com](mailto:berger@khlaw.com)  
1001 G Street, N.W., Suite 500 West | Washington, D.C. 20001

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**From:** Berger, Tom C.  
**Sent:** Monday, November 18, 2019 1:17 PM  
**To:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>  
**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>  
**Subject:** RE: **Ex. 4 CBI**

Hi Jeff –

The PMN submitter asked me to reach out to you to see if we can schedule a conference call (including EPA, K&H, and the submitter) on this case re status and pathforward.

Thanks - Tom

---

**From:** Bauer, Jeff <Bauer.Jeff@epa.gov>  
**Sent:** Friday, March 29, 2019 5:43 PM  
**To:** Berger, Tom C. <Berger@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>  
**Cc:** Daniels, Rhys G. <daniels@khlaw.com>  
**Subject:** RE: **Ex. 4 CBI**

Tom,  
I set the meeting up for Wednesday April 3, at 11 am. RAD has accepted the invitation for that time.

Jeff Bauer - Program Manager  
United States Environmental Protection Agency (USEPA)  
Office of Pollution Prevention and Toxics (OPPT)  
New Chemicals Program (7405M)  
<http://www.epa.gov/oppt/newchemicals/>

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Washington, DC 20004  
Phone: 202-564-9042, Fax: 202-564-9490

---

**From:** Bauer, Jeff  
**Sent:** Tuesday, March 26, 2019 11:37 AM  
**To:** 'Berger, Tom C.' <Berger@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>  
**Cc:** Daniels, Rhys G. <daniels@khlaw.com>  
**Subject:** RE: **Ex. 4 CBI**

Tom, I left you a voice message, I am seeing what time it best for RAD to be part of the call.

Jeff Bauer - Program Manager  
United States Environmental Protection Agency (USEPA)  
Office of Pollution Prevention and Toxics (OPPT)  
New Chemicals Program (7405M)  
<http://www.epa.gov/oppt/newchemicals/>

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1201 Constitution Ave., NW  
Washington, DC 20004  
Phone: 202-564-9042, Fax: 202-564-9490

---

**From:** Berger, Tom C. <Berger@khlaw.com>  
**Sent:** Tuesday, March 26, 2019 11:30 AM  
**To:** Bauer, Jeff <Bauer.Jeff@epa.gov>; Schweer, Greg <Schweer.Greg@epa.gov>  
**Cc:** Daniels, Rhys G. <daniels@khlaw.com>  
**Subject:** RE: **Ex. 4 CBI**

Hi folks –

Just thought I would check in with you on this.

Thanks again - Tom

---

**From:** Berger, Tom C.  
**Sent:** Friday, March 22, 2019 2:12 PM  
**To:** 'Bauer.jeff@Epa.gov' <Bauer.jeff@Epa.gov>; 'Schweer, Greg' <Schweer.Greg@epa.gov>  
**Cc:** Daniels, Rhys G. <daniels@khlaw.com>  
**Subject:** **Ex. 4 CBI**

Hi folks –

I hope you are doing well. Jeff – this is the PMN case that my colleague, Dr. Rhys Daniels, spoke with you about earlier this week.

The issue is development of data needed to amend the existing section 5(e) order for this substance to add an additional use, and EPA approval of protocols for same. Would the Agency be available for a short conference call on this on one of the following days?:

- March 27 (except 12-2 ET)
- April 2
- April 3
- April 4

This is becoming more urgent from a commercial standpoint.

Thanks much - Tom

Thomas C. Berger  
Partner  
tel: 202.434.4285 | fax: 202.434.4646 | [berger@khlaw.com](mailto:berger@khlaw.com)  
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Message

---

**From:** Bauer, Jeff [Bauer.Jeff@epa.gov]  
**Sent:** 5/7/2020 8:03:33 PM  
**To:** Berger, Tom C. [Berger@khlaw.com]  
**CC:** Price, Amanda [price@khlaw.com]; Schweer, Greg [Schweer.Greg@epa.gov]; Daniels, Rhys G. [daniels@khlaw.com]  
**Subject:** RE: **Ex. 4 CBI**

Tom, I hope you hanging in there as well, I have an email out to see if I can get a status update on the Assessor and to address you questions sent into CDX for a meeting.

Jeff

Jeff Bauer - Program Manager  
United States Environmental Protection Agency (USEPA)  
Office of Pollution Prevention and Toxics (OPPT)  
New Chemicals Program (7405M)  
<http://www.epa.gov/oppt/newchems/>

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Phone: 202-564-9042, Fax: 202-564-9490

---

**From:** Berger, Tom C. <Berger@khlaw.com>  
**Sent:** Thursday, May 07, 2020 1:57 PM  
**To:** Bauer, Jeff <Bauer.Jeff@epa.gov>  
**Cc:** Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>  
**Subject:** RE: **Ex. 4 CBI**

Hi Jeff – Just touching base as the submitter has requested a status update.

Thanks again - Tom

---

**From:** Berger, Tom C.  
**Sent:** Tuesday, May 5, 2020 11:56 AM  
**To:** 'Bauer, Jeff' <Bauer.Jeff@epa.gov>  
**Cc:** Price, Amanda <price@khlaw.com>; 'Schweer, Greg' <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>  
**Subject:** RE: **Ex. 4 CBI**

Hi Jeff – Just checking in on this – thanks - Tom

---

**From:** Berger, Tom C.  
**Sent:** Wednesday, April 29, 2020 11:12 AM  
**To:** Bauer, Jeff <Bauer.Jeff@epa.gov>  
**Cc:** Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>  
**Subject:** RE: **Ex. 4 CBI**

Hi Jeff –



I just thought I would check in on this and see if the Agency needs any additional information.

Thanks again and best regards,  
Tom

Thomas C. Berger  
Partner  
tel: 202.434.4285 | fax: 202.434.4646 | [berger@khlaw.com](mailto:berger@khlaw.com)  
1001 G Street, N.W., Suite 500 West | Washington, D.C. 20001

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**From:** Berger, Tom C.  
**Sent:** Thursday, April 23, 2020 7:13 PM  
**To:** 'Bauer, Jeff' <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>  
**Cc:** Price, Amanda <[price@khlaw.com](mailto:price@khlaw.com)>; Schweer, Greg <[Schweer.Greg@epa.gov](mailto:Schweer.Greg@epa.gov)>; Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>  
**Subject:** RE: **Ex. 4 CBI**

Jeff - thanks much.

Your recent voicemail and follow-up email indicated that the EPA Chemist has evaluated the **Ex. 4 CBI** study" on **Ex. 4 CBI** **Ex. 4 CBI** but that the reviewer did have a few questions and comments:

**Ex. 4 CBI**

# Ex. 4 CBI

To specifically answer the Chemist's questions:

# Ex. 4 CBI

# Ex. 4 CBI

\* \* \*

We trust that you find this information useful in resolved all outstanding issues. As always, if you have any questions please do not hesitate to contact us.

Best regards,  
Tom

Thomas C. Berger  
Partner  
tel: 202.434.4285 | fax: 202.434.4646 | [berger@khlaw.com](mailto:berger@khlaw.com)  
1001 G Street, N.W., Suite 500 West | Washington, D.C. 20001

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**From:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>  
**Sent:** Tuesday, April 21, 2020 5:17 PM  
**To:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>; Berger, Tom C. <[Berger@khlaw.com](mailto:Berger@khlaw.com)>  
**Cc:** Price, Amanda <[price@khlaw.com](mailto:price@khlaw.com)>; Schweer, Greg <[Schweer.Greg@epa.gov](mailto:Schweer.Greg@epa.gov)>  
**Subject:** RE: **Ex. 4 CBI**

I am moving forward with the review based on the information I have on the two studies, I wanted to share with you her comments on the test. **Ex. 4 CBI**

**Ex. 4 CBI** RAD has the information and I am trying to get them to do the risk assessment based on **Ex. 4 CBI**

Jeff Bauer - Program Manager

United States Environmental Protection Agency (USEPA)  
Office of Pollution Prevention and Toxics (OPPT)  
New Chemicals Program (7405M)  
<http://www.epa.gov/oppt/newchems/>

EPA East Building, room 4133M  
1201 Constitution Ave., NW  
Washington, DC 20004  
Phone: 202-564-9042, Fax: 202-564-9490

---

**From:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>  
**Sent:** Tuesday, April 21, 2020 4:58 PM  
**To:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>; Berger, Tom C. <[Berger@khlaw.com](mailto:Berger@khlaw.com)>  
**Cc:** Price, Amanda <[price@khlaw.com](mailto:price@khlaw.com)>; Schweer, Greg <[Schweer.Greg@epa.gov](mailto:Schweer.Greg@epa.gov)>  
**Subject:** RE: **Ex. 4 CBI**

Jeff,

As always, we hope that all is well.

Per your recent voicemail and follow-up email concerning the **Ex. 4 CBI** case, we understand that the chemist has two questions concerning **Ex. 4 CBI**

**Ex. 4 CBI**

Thanks in advance for your response.

Rhys G. Daniels, Ph.D.  
Staff Scientist  
tel: +1 202.434.4270 | fax: +1 202.434.4646 | [daniels@khlaw.com](mailto:daniels@khlaw.com)  
1001 G Street NW, Suite 500 West | Washington, DC 20001



---

**From:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>  
**Sent:** Thursday, April 16, 2020 1:02 PM  
**To:** Berger, Tom C. <[Berger@khlaw.com](mailto:Berger@khlaw.com)>  
**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>; Price, Amanda <[price@khlaw.com](mailto:price@khlaw.com)>; Schweer, Greg <[Schweer.Greg@epa.gov](mailto:Schweer.Greg@epa.gov)>  
**Subject:** RE: **Ex. 4 CBI**

Tom,

The chemist sent me a memo [Ex. 4 CBI] and they had two questions, I called and left you a message today [Ex. 4 CBI] I sent RAD a request last week to update the HH assessment [Ex. 4 CBI] [Ex. 4 CBI] as in my April 4, 2020 email to you. I have two emails into RAD on this case and will try an update you again in a week or so. I requested RAD set up a date with me to have a meeting to discuss how to proceed with this PMN.

Thanks  
Jeff

Jeff Bauer - Program Manager  
United States Environmental Protection Agency (USEPA)  
Office of Pollution Prevention and Toxics (OPPT)  
New Chemicals Program (7405M)  
<http://www.epa.gov/oppt/newchems/>

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Washington, DC 20004  
Phone: 202-564-9042, Fax: 202-564-9490

---

**From:** Berger, Tom C. <[Berger@khlaw.com](mailto:Berger@khlaw.com)>  
**Sent:** Thursday, April 16, 2020 12:28 PM  
**To:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>  
**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>; Price, Amanda <[price@khlaw.com](mailto:price@khlaw.com)>; Schweer, Greg <[Schweer.Greg@epa.gov](mailto:Schweer.Greg@epa.gov)>  
**Subject:** RE: [Ex. 4 CBI]

Hi Jeff –

I hope that all is well.

Just checking in re status update. A non-CBI-containing email from you would probably be the best (if needed at some later time we can use EPA's new CBI via email authorization form if the submitter agrees).

Thanks again – Tom

---

**From:** Berger, Tom C.  
**Sent:** Wednesday, April 8, 2020 11:06 AM  
**To:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>; Schweer, Greg <[Schweer.Greg@epa.gov](mailto:Schweer.Greg@epa.gov)>  
**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>; Price, Amanda <[price@khlaw.com](mailto:price@khlaw.com)>  
**Subject:** RE: [Ex. 4 CBI]

Jeff – thanks much for the update. Hope you and all at EPA are staying safe.

Tom

---

**From:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>  
**Sent:** Wednesday, April 8, 2020 11:03 AM  
**To:** Berger, Tom C. <[Berger@khlaw.com](mailto:Berger@khlaw.com)>; Schweer, Greg <[Schweer.Greg@epa.gov](mailto:Schweer.Greg@epa.gov)>

Cc: Daniels, Rhys G. <daniels@khlaw.com>; Price, Amanda <price@khlaw.com>

Subject: RE: **Ex. 4 CBI**

Tom,

# Ex. 4 CBI

I will follow up with you next wed with a status update.

Jeff Bauer - Program Manager  
United States Environmental Protection Agency (USEPA)  
Office of Pollution Prevention and Toxics (OPPT)  
New Chemicals Program (7405M)  
<http://www.epa.gov/oppt/newchems/>

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Phone: 202-564-9042, Fax: 202-564-9490

---

**From:** Berger, Tom C. <Berger@khlaw.com>

**Sent:** Wednesday, April 08, 2020 10:48 AM

**To:** Schweer, Greg <Schweer.Greg@epa.gov>

**Cc:** Daniels, Rhys G. <daniels@khlaw.com>; Bauer, Jeff <Bauer.Jeff@epa.gov>; Price, Amanda <price@khlaw.com>

**Subject:** RE: **Ex. 4 CBI**

Hi Greg –

I was just going through my to-do list and thought I would circle back on these two cases. I hope everyone is hanging in there.

Thanks again – Tom

---

**From:** Berger, Tom C.

**Sent:** Monday, March 30, 2020 3:46 PM

**To:** Schweer, Greg <Schweer.Greg@epa.gov>

**Cc:** Daniels, Rhys G. <daniels@khlaw.com>; Bauer, Jeff <Bauer.Jeff@epa.gov>; Price, Amanda <price@khlaw.com>

**Subject:** RE: **Ex. 4 CBI**

Greg / all – completely understood – thank you so much.

Tom

---

**From:** Schweer, Greg <Schweer.Greg@epa.gov>

**Sent:** Monday, March 30, 2020 3:42 PM

**To:** Berger, Tom C. <Berger@khlaw.com>

**Cc:** Daniels, Rhys G. <daniels@khlaw.com>; Bauer, Jeff <Bauer.Jeff@epa.gov>

**Subject:** RE: **Ex. 4 CBI**

Hi Tom.

I am not ignoring you. I did check with Jeff Bauer early last week on this case. He filled me in on the requests he had made of RAD to review submitted test data and your request for a meeting. However, believe it or not, we have been having issues reliably being able to access our CBI-secure LAN. This hampers our ability to efficiently complete work. I will check on the status of your case as soon as I can.

---

**From:** Berger, Tom C. <Berger@khlaw.com>  
**Sent:** Monday, March 30, 2020 11:51 AM  
**To:** Schweer, Greg <Schweer.Greg@epa.gov>  
**Cc:** Daniels, Rhys G. <daniels@khlaw.com>  
**Subject:** RE: Ex. 4 CBI

Hi Greg –

Hope all is well.

Just thought I would check in with you on the Ex. 4 CBI LVEA (Lauren Davis) and Ex. 4 CBI with Jeff Bauer.

Thanks all always - Tom

---

**From:** Berger, Tom C.  
**Sent:** Tuesday, March 24, 2020 11:12 AM  
**To:** Schweer, Greg <Schweer.Greg@epa.gov>  
**Cc:** Daniels, Rhys G. <daniels@khlaw.com>  
**Subject:** RE: Ex. 4 CBI

Greg – thanks so much as always. I also have an LVE with Lauren Davis Ex. 4 CBI held up in the process. Lauren has been responsive but the case has stalled (again, however, I understand the challenges you are facing).

These are my two “priority” cases.

Tom

---

**From:** Schweer, Greg <Schweer.Greg@epa.gov>  
**Sent:** Tuesday, March 24, 2020 11:07 AM  
**To:** Berger, Tom C. <Berger@khlaw.com>  
**Cc:** Daniels, Rhys G. <daniels@khlaw.com>  
**Subject:** Re: Ex. 4 CBI

Tom,

Yes, things are a bit crazy. I will check into the case status today or tomorrow.

Sent from my iPhone

On Mar 24, 2020, at 10:48 AM, Berger, Tom C. <Berger@khlaw.com> wrote:

Hi Greg –

Obviously things are crazy and I don't want to push Jeff too hard but no response from Jeff on this case for a month.

Hang in there....

Tom

---

**From:** Berger, Tom C.  
**Sent:** Monday, March 23, 2020 6:22 PM  
**To:** Bauer, Jeff <Bauer.Jeff@epa.gov>  
**Cc:** Daniels, Rhys G. <daniels@khlaw.com>  
**Subject:** RE: **Ex. 4 CBI**

Hi Jeff –

Apologies – just want to make sure you are getting these emails. Understand if there are delays.

Tom

---

**From:** Berger, Tom C.  
**Sent:** Thursday, March 19, 2020 5:22 PM  
**To:** Bauer, Jeff <Bauer.Jeff@epa.gov>  
**Cc:** Daniels, Rhys G. <daniels@khlaw.com>  
**Subject:** RE: **Ex. 4 CBI**

Hi Jeff – checking in again – thanks - Tom

---

**From:** Berger, Tom C.  
**Sent:** Monday, March 16, 2020 1:40 PM  
**To:** Bauer, Jeff <Bauer.Jeff@epa.gov>  
**Cc:** Daniels, Rhys G. <daniels@khlaw.com>  
**Subject:** RE: **Ex. 4 CBI**

Hi Jeff –

I know things are crazy but checking in again – thanks - Tom

---

**From:** Berger, Tom C.  
**Sent:** Wednesday, March 11, 2020 3:43 PM  
**To:** Bauer, Jeff <Bauer.Jeff@epa.gov>  
**Cc:** Daniels, Rhys G. <daniels@khlaw.com>  
**Subject:** RE: **Ex. 4 CBI**

Hi Jeff –

Checking in again - thanks

---

**From:** Berger, Tom C.  
**Sent:** Friday, March 6, 2020 1:33 PM  
**To:** Bauer, Jeff <Bauer.Jeff@epa.gov>



**Cc:** Daniels, Rhys G. <daniels@khlaw.com>

**Subject:** RE: **Ex. 4 CBI**

Hi Jeff –

The submitter is quite anxious – can we touch base next week?

Thanks much - Tom

---

**From:** Berger, Tom C.

**Sent:** Tuesday, February 25, 2020 9:08 AM

**To:** Bauer, Jeff <Bauer.Jeff@epa.gov>

**Cc:** Daniels, Rhys G. <daniels@khlaw.com>

**Subject:** RE: **Ex. 4 CBI**

Hi Jeff –

Just checking in on this – thanks - Tom

---

**From:** Berger, Tom C.

**Sent:** Thursday, February 20, 2020 12:18 PM

**To:** Bauer, Jeff <Bauer.Jeff@epa.gov>

**Cc:** Daniels, Rhys G. <daniels@khlaw.com>

**Subject:** RE: **Ex. 4 CBI**

Hi Jeff –

I hope that all is well.

Per our discussions, the submitter has modified the questions to focus on toxicity/risk issues and submitted them via CDX yesterday. Can we start looking at conference call dates the week of March 9?

Thanks and best regards,

Tom

Thomas C. Berger

Partner

tel: 202.434.4285 | fax: 202.434.4646 | [berger@khlaw.com](mailto:berger@khlaw.com)

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**From:** Berger, Tom C.

**Sent:** Wednesday, January 29, 2020 11:41 AM

**To:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>  
**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>  
**Subject:** RE: **Ex. 4 CBI**

Hi Jeff –

Apologies we keep playing phone tag – can we discuss how to convert the below questions into questions that would be acceptable to RAD so we can schedule a call with you and RAD? Your voicemail suggested the below are more legal/regulatory than risk-based questions. We still need the below questions answered – perhaps we tee up the more scientific ones for RAD then have the call to address both types of questions. The submitter is under growing commercial pressure.

Thanks much again - Tom

---

**From:** Berger, Tom C.  
**Sent:** Monday, January 20, 2020 3:50 PM  
**To:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>  
**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>  
**Subject:** RE: **Ex. 4 CBI**

Hi Jeff –

Apologies that we could not connect last week. Let's try to touch base tomorrow (Tuesday) if possible to discuss how to move this forward.

Thanks again – Tom

Thomas C. Berger  
Partner  
tel: 202.434.4285 | fax: 202.434.4646 | [berger@khlaw.com](mailto:berger@khlaw.com)  
1001 G Street, N.W., Suite 500 West | Washington, D.C. 20001

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**From:** Berger, Tom C.  
**Sent:** Monday, January 13, 2020 2:50 PM  
**To:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>  
**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>  
**Subject:** RE: **Ex. 4 CBI**  
**Importance:** High

Hi Jeff –

Following is the list of questions we are considering submitting through CDX. Please let me know if these look ok.

Thanks again and best regards,  
Tom

\* \* \*

*(1) Based on review of the submitted physical-chemical properties test data, does EPA now agree that use [Ex. 4 CBI] as described in the PMN poses no unreasonable risk of injury and so plans to revoke the consent order?*

*(2) If so, what is the process for revoking the current consent order? Does the submitter now need to request that EPA revoke the order, or will EPA itself initiate revocation? What is the expected timing for revocation? How would EPA communicate such revocation?*

*(3) How would revocation of the consent order impact the final SNUR for the subject substance?*

*(4) Would a SNUN be a more expedient approach?*

\* \* \*

---

**From:** Bauer, Jeff <Bauer.Jeff@epa.gov>  
**Sent:** Wednesday, January 8, 2020 8:56 AM  
**To:** Berger, Tom C. <Berger@khlaw.com>  
**Cc:** Daniels, Rhys G. <daniels@khlaw.com>  
**Subject:** RE: [Ex. 4 CBI]

Tom, I am expecting information from the engineer today or tomorrow on the [Ex. 4 CBI] test, I left you a message. There is a new procedure for us to set up meeting with RAD. I am to have the submitter send in a list of questions for RAD, they will assign someone up there as a Lead person who has two weeks and will set a date for when we can have a meeting. This may be our best route to other than just me bugging them to get things done. There were a series of emails on this case last week but now everyone is back from the holidays I am trying to get this case moving again.

Jeff Bauer - Program Manager  
United States Environmental Protection Agency (USEPA)  
Office of Pollution Prevention and Toxics (OPPT)  
New Chemicals Program (7405M)  
<http://www.epa.gov/oppt/newchems/>

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1201 Constitution Ave., NW  
Washington, DC 20004  
Phone: 202-564-9042, Fax: 202-564-9490

---

**From:** Berger, Tom C. <Berger@khlaw.com>  
**Sent:** Tuesday, January 07, 2020 4:16 PM  
**To:** Bauer, Jeff <Bauer.Jeff@epa.gov>

**Cc:** Daniels, Rhys G. <daniels@khlaw.com>

**Subject:** RE: **Ex. 4 CBI**

Hi Jeff –

I hope you had a great holiday! The client was wondering if we could have a conference call on this, this week or next. Please advise.

Thanks much – Tom

Thomas C. Berger

Partner

tel: 202.434.4285 | fax: 202.434.4646 | [berger@khlaw.com](mailto:berger@khlaw.com)  
1001 G Street, N.W., Suite 500 West | Washington, D.C. 20001

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**From:** Berger, Tom C.

**Sent:** Tuesday, December 10, 2019 2:10 PM

**To:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>

**Cc:** Daniels, Rhys G. <daniels@khlaw.com>

**Subject:** RE: **Ex. 4 CBI**

Hi Jeff –

Just checking back in – thanks - Tom

---

**From:** Berger, Tom C.

**Sent:** Thursday, December 5, 2019 9:46 AM

**To:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>

**Cc:** Daniels, Rhys G. <daniels@khlaw.com>

**Subject:** RE: **Ex. 4 CBI**

Hi Jeff –

When we spoke before Thanksgiving (I hope you had a great one!) you indicated that the reports were being reviewed and that I should reach out to you in early December.

Is there any update?

Thanks much and best regards – Tom

Thomas C. Berger

Partner

tel: 202.434.4285 | fax: 202.434.4646 | [berger@khlaw.com](mailto:berger@khlaw.com)  
1001 G Street, N.W., Suite 500 West | Washington, D.C. 20001

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**From:** Berger, Tom C.  
**Sent:** Monday, November 18, 2019 1:17 PM  
**To:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>  
**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>  
**Subject:** RE: **Ex. 4 CBI**

Hi Jeff –

The PMN submitter asked me to reach out to you to see if we can schedule a conference call (including EPA, K&H, and the submitter) on this case re status and pathforward.

Thanks - Tom

---

**From:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>  
**Sent:** Friday, March 29, 2019 5:43 PM  
**To:** Berger, Tom C. <[Berger@khlaw.com](mailto:Berger@khlaw.com)>; Schweer, Greg <[Schweer.Greg@epa.gov](mailto:Schweer.Greg@epa.gov)>  
**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>  
**Subject:** RE: **Ex. 4 CBI**

Tom,  
I set the meeting up for Wednesday April 3, at 11 am. RAD has accepted the invitation for that time.

Jeff Bauer - Program Manager  
United States Environmental Protection Agency (USEPA)  
Office of Pollution Prevention and Toxics (OPPT)  
New Chemicals Program (7405M)  
<http://www.epa.gov/oppt/newchemicals/>

EPA East Building, room 4133M  
1201 Constitution Ave., NW  
Washington, DC 20004  
Phone: 202-564-9042, Fax: 202-564-9490

---

**From:** Bauer, Jeff  
**Sent:** Tuesday, March 26, 2019 11:37 AM  
**To:** 'Berger, Tom C.' <[Berger@khlaw.com](mailto:Berger@khlaw.com)>; Schweer, Greg <[Schweer.Greg@epa.gov](mailto:Schweer.Greg@epa.gov)>  
**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>  
**Subject:** RE: **Ex. 4 CBI**

Tom, I left you a voice message, I am seeing what time it best for RAD to be part of the call.

Jeff Bauer - Program Manager  
United States Environmental Protection Agency (USEPA)  
Office of Pollution Prevention and Toxics (OPPT)  
New Chemicals Program (7405M)  
<http://www.epa.gov/oppt/newchemicals/>

EPA East Building, room 4133M  
1201 Constitution Ave., NW  
Washington, DC 20004  
Phone: 202-564-9042, Fax: 202-564-9490

---

**From:** Berger, Tom C. <[Berger@khlaw.com](mailto:Berger@khlaw.com)>  
**Sent:** Tuesday, March 26, 2019 11:30 AM  
**To:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>; Schweer, Greg <[Schweer.Greg@epa.gov](mailto:Schweer.Greg@epa.gov)>  
**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>  
**Subject:** RE: **Ex. 4 CBI**

Hi folks –

Just thought I would check in with you on this.

Thanks again - Tom

---

**From:** Berger, Tom C.  
**Sent:** Friday, March 22, 2019 2:12 PM  
**To:** 'Bauer.jeff@Epa.gov' <[Bauer.jeff@Epa.gov](mailto:Bauer.jeff@Epa.gov)>; 'Schweer, Greg' <[Schweer.Greg@epa.gov](mailto:Schweer.Greg@epa.gov)>  
**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>  
**Subject:** **Ex. 4 CBI**

Hi folks –

I hope you are doing well. Jeff – this is the PMN case that my colleague, Dr. Rhys Daniels, spoke with you about earlier this week.

The issue is development of data needed to amend the existing section 5(e) order for this substance to add an additional use, and EPA approval of protocols for same. Would the Agency be available for a short conference call on this on one of the following days?:

- March 27 (except 12-2 ET)
- April 2
- April 3
- April 4

This is becoming more urgent from a commercial standpoint.

Thanks much - Tom

Thomas C. Berger  
Partner

tel: 202.434.4285 | fax: 202.434.4646 | [berger@khlaw.com](mailto:berger@khlaw.com)  
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Message

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**From:** Berger, Tom C. [Berger@khlaw.com]  
**Sent:** 5/7/2020 5:56:48 PM  
**To:** Bauer, Jeff [Bauer.Jeff@epa.gov]  
**CC:** Price, Amanda [price@khlaw.com]; Schweer, Greg [Schweer.Greg@epa.gov]; Daniels, Rhys G. [daniels@khlaw.com]  
**Subject:** RE: **Ex. 4 CBI**

Hi Jeff – Just touching base as the submitter has requested a status update.

Thanks again - Tom

---

**From:** Berger, Tom C.  
**Sent:** Tuesday, May 5, 2020 11:56 AM  
**To:** 'Bauer, Jeff' <Bauer.Jeff@epa.gov>  
**Cc:** Price, Amanda <price@khlaw.com>; 'Schweer, Greg' <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>  
**Subject:** RE: **Ex. 4 CBI**

Hi Jeff – Just checking in on this – thanks - Tom

---

**From:** Berger, Tom C.  
**Sent:** Wednesday, April 29, 2020 11:12 AM  
**To:** Bauer, Jeff <Bauer.Jeff@epa.gov>  
**Cc:** Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>  
**Subject:** RE: **Ex. 4 CBI**

Hi Jeff –

I just thought I would check in on this and see if the Agency needs any additional information.

Thanks again and best regards,  
Tom

Thomas C. Berger  
Partner  
tel: 202.434.4285 | fax: 202.434.4646 | [berger@khlaw.com](mailto:berger@khlaw.com)  
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**From:** Berger, Tom C.  
**Sent:** Thursday, April 23, 2020 7:13 PM  
**To:** 'Bauer, Jeff' <Bauer.Jeff@epa.gov>



Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>

Subject: RE: Ex. 4 CBI

Jeff - thanks much.

Your recent voicemail and follow-up email indicated that the EPA Chemist has evaluated the Ex. 4 CBI study" on Ex. 4 CBI Ex. 4 CBI but that the reviewer did have a few questions and comments:

**Ex. 4 CBI**

To specifically answer the Chemist's questions:

**Ex. 4 CBI**

# Ex. 4 CBI

\* \* \*

We trust that you find this information useful in resolved all outstanding issues. As always, if you have any questions please do not hesitate to contact us.

Best regards,  
Tom

Thomas C. Berger  
Partner  
tel: 202.434.4285 | fax: 202.434.4646 | [berger@khlaw.com](mailto:berger@khlaw.com)  
1001 G Street, N.W., Suite 500 West | Washington, D.C. 20001

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**From:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>  
**Sent:** Tuesday, April 21, 2020 5:17 PM  
**To:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>; Berger, Tom C. <[Berger@khlaw.com](mailto:Berger@khlaw.com)>  
**Cc:** Price, Amanda <[price@khlaw.com](mailto:price@khlaw.com)>; Schweer, Greg <[Schweer.Greg@epa.gov](mailto:Schweer.Greg@epa.gov)>  
**Subject:** RE: Ex. 4 CBI

I am moving forward with the review based on the information I have on the two studies, I wanted to share with you her comments on the test. Ex. 4 CBI

Ex. 4 CBI RAD has the information and I am trying to get them to do the risk assessment based on Ex. 4 CBI

Jeff Bauer - Program Manager  
United States Environmental Protection Agency (USEPA)  
Office of Pollution Prevention and Toxics (OPPT)  
New Chemicals Program (7405M)  
<http://www.epa.gov/oppt/newchems/>

EPA East Building, room 4133M  
1201 Constitution Ave., NW  
Washington, DC 20004  
Phone: 202-564-9042, Fax: 202-564-9490

---

**From:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>  
**Sent:** Tuesday, April 21, 2020 4:58 PM  
**To:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>; Berger, Tom C. <[Berger@khlaw.com](mailto:Berger@khlaw.com)>  
**Cc:** Price, Amanda <[price@khlaw.com](mailto:price@khlaw.com)>; Schweer, Greg <[Schweer.Greg@epa.gov](mailto:Schweer.Greg@epa.gov)>  
**Subject:** RE: Ex. 4 CBI

Jeff,

As always, we hope that all is well.

Per your recent voicemail and follow-up email concerning the Ex. 4 CBI case, we understand that the chemist has two questions concerning Ex. 4 CBI

Ex. 4 CBI

# Ex. 4 CBI

Thanks in advance for your response.

Rhys G. Daniels, Ph.D.  
Staff Scientist

tel: +1 202.434.4270 | fax: +1 202.434.4646 | [daniels@khlaw.com](mailto:daniels@khlaw.com)  
1001 G Street NW, Suite 500 West | Washington, DC 20001



---

**From:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>  
**Sent:** Thursday, April 16, 2020 1:02 PM  
**To:** Berger, Tom C. <[Berger@khlaw.com](mailto:Berger@khlaw.com)>  
**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>; Price, Amanda <[price@khlaw.com](mailto:price@khlaw.com)>; Schweer, Greg <[Schweer.Greg@epa.gov](mailto:Schweer.Greg@epa.gov)>  
**Subject:** RE: **Ex. 4 CBI**

Tom,

The chemist sent me a memo **Ex. 4 CBI** and they had two questions, I called and left you a message today **Ex. 4 CBI** I sent RAD a request last week to update the HH assessment **Ex. 4 CBI** **Ex. 4 CBI** as in my April 4, 2020 email to you. I have two emails into RAD on this case and will try an update you again in a week or so. I requested RAD set up a date with me to have a meeting to discuss how to proceed with this PMN.

Thanks  
Jeff

Jeff Bauer - Program Manager  
United States Environmental Protection Agency (USEPA)  
Office of Pollution Prevention and Toxics (OPPT)  
New Chemicals Program (7405M)  
<http://www.epa.gov/oppt/newchemicals/>

EPA East Building, room 4133M  
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Washington, DC 20004  
Phone: 202-564-9042, Fax: 202-564-9490

---

**From:** Berger, Tom C. <Berger@khlaw.com>  
**Sent:** Thursday, April 16, 2020 12:28 PM  
**To:** Bauer, Jeff <Bauer.Jeff@epa.gov>  
**Cc:** Daniels, Rhys G. <daniels@khlaw.com>; Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>  
**Subject:** RE: **Ex. 4 CBI**

Hi Jeff –

I hope that all is well.

Just checking in re status update. A non-CBI-containing email from you would probably be the best (if needed at some later time we can use EPA's new CBI via email authorization form if the submitter agrees).

Thanks again – Tom

---

**From:** Berger, Tom C.  
**Sent:** Wednesday, April 8, 2020 11:06 AM  
**To:** Bauer, Jeff <Bauer.Jeff@epa.gov>; Schweer, Greg <Schweer.Greg@epa.gov>  
**Cc:** Daniels, Rhys G. <daniels@khlaw.com>; Price, Amanda <price@khlaw.com>  
**Subject:** RE: **Ex. 4 CBI**

Jeff – thanks much for the update. Hope you and all at EPA are staying safe.

Tom

---

**From:** Bauer, Jeff <Bauer.Jeff@epa.gov>  
**Sent:** Wednesday, April 8, 2020 11:03 AM  
**To:** Berger, Tom C. <Berger@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>  
**Cc:** Daniels, Rhys G. <daniels@khlaw.com>; Price, Amanda <price@khlaw.com>  
**Subject:** RE: **Ex. 4 CBI**

Tom,

# Ex. 4 CBI

I will follow up with you next wed with a status update.

Jeff Bauer - Program Manager  
United States Environmental Protection Agency (USEPA)  
Office of Pollution Prevention and Toxics (OPPT)  
New Chemicals Program (7405M)  
<http://www.epa.gov/oppt/newchemicals/>

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1201 Constitution Ave., NW  
Washington, DC 20004  
Phone: 202-564-9042, Fax: 202-564-9490

---

**From:** Berger, Tom C. <Berger@khlaw.com>  
**Sent:** Wednesday, April 08, 2020 10:48 AM  
**To:** Schweer, Greg <Schweer.Greg@epa.gov>  
**Cc:** Daniels, Rhys G. <daniels@khlaw.com>; Bauer, Jeff <Bauer.Jeff@epa.gov>; Price, Amanda <price@khlaw.com>  
**Subject:** RE: **Ex. 4 CBI**

Hi Greg –

I was just going through my to-do list and thought I would circle back on these two cases. I hope everyone is hanging in there.

Thanks again – Tom

---

**From:** Berger, Tom C.  
**Sent:** Monday, March 30, 2020 3:46 PM  
**To:** Schweer, Greg <Schweer.Greg@epa.gov>  
**Cc:** Daniels, Rhys G. <daniels@khlaw.com>; Bauer, Jeff <Bauer.Jeff@epa.gov>; Price, Amanda <price@khlaw.com>  
**Subject:** RE: **Ex. 4 CBI**

Greg / all – completely understood – thank you so much.

Tom

---

**From:** Schweer, Greg <Schweer.Greg@epa.gov>  
**Sent:** Monday, March 30, 2020 3:42 PM  
**To:** Berger, Tom C. <Berger@khlaw.com>  
**Cc:** Daniels, Rhys G. <daniels@khlaw.com>; Bauer, Jeff <Bauer.Jeff@epa.gov>  
**Subject:** RE: **Ex. 4 CBI**

Hi Tom.

I am not ignoring you. I did check with Jeff Bauer early last week on this case. He filled me in on the requests he had made of RAD to review submitted test data and your request for a meeting. However, believe it or not, we have been having issues reliably being able to access our CBI-secure LAN. This hampers our ability to efficiently complete work. I will check on the status of your case as soon as I can.

---

**From:** Berger, Tom C. <Berger@khlaw.com>  
**Sent:** Monday, March 30, 2020 11:51 AM  
**To:** Schweer, Greg <Schweer.Greg@epa.gov>  
**Cc:** Daniels, Rhys G. <daniels@khlaw.com>  
**Subject:** RE: **Ex. 4 CBI**

Hi Greg –

Hope all is well.

Just thought I would check in with you on the **Ex. 4 CBI** LVEA (Lauren Davis) and **Ex. 4 CBI** **Ex. 4 CBI** with Jeff Bauer.

Thanks all always - Tom

---

**From:** Berger, Tom C.  
**Sent:** Tuesday, March 24, 2020 11:12 AM  
**To:** Schweer, Greg <Schweer.Greg@epa.gov>  
**Cc:** Daniels, Rhys G. <daniels@khlaw.com>  
**Subject:** RE: **Ex. 4 CBI**

Greg – thanks so much as always. I also have an LVE with Lauren Davis **Ex. 4 CBI** held up in the process. Lauren has been responsive but the case has stalled (again, however, I understand the challenges you are facing).

These are my two “priority” cases.

Tom

---

**From:** Schweer, Greg <Schweer.Greg@epa.gov>  
**Sent:** Tuesday, March 24, 2020 11:07 AM  
**To:** Berger, Tom C. <Berger@khlaw.com>  
**Cc:** Daniels, Rhys G. <daniels@khlaw.com>  
**Subject:** Re: **Ex. 4 CBI**

Tom,

Yes, things are a bit crazy. I will check into the case status today or tomorrow.

Sent from my iPhone

On Mar 24, 2020, at 10:48 AM, Berger, Tom C. <Berger@khlaw.com> wrote:

Hi Greg –

Obviously things are crazy and I don't want to push Jeff too hard but no response from Jeff on this case for a month.

Hang in there....

Tom

---

**From:** Berger, Tom C.  
**Sent:** Monday, March 23, 2020 6:22 PM  
**To:** Bauer, Jeff <Bauer.Jeff@epa.gov>  
**Cc:** Daniels, Rhys G. <daniels@khlaw.com>  
**Subject:** RE: **Ex. 4 CBI**

Hi Jeff –

Apologies – just want to make sure you are getting these emails. Understand if there are delays.

Tom

---

**From:** Berger, Tom C.  
**Sent:** Thursday, March 19, 2020 5:22 PM  
**To:** Bauer, Jeff <Bauer.Jeff@epa.gov>  
**Cc:** Daniels, Rhys G. <daniels@khlaw.com>  
**Subject:** RE: **Ex. 4 CBI**

Hi Jeff – checking in again – thanks - Tom

---

**From:** Berger, Tom C.  
**Sent:** Monday, March 16, 2020 1:40 PM  
**To:** Bauer, Jeff <Bauer.Jeff@epa.gov>  
**Cc:** Daniels, Rhys G. <daniels@khlaw.com>  
**Subject:** RE: **Ex. 4 CBI**

Hi Jeff –

I know things are crazy but checking in again – thanks - Tom

---

**From:** Berger, Tom C.  
**Sent:** Wednesday, March 11, 2020 3:43 PM  
**To:** Bauer, Jeff <Bauer.Jeff@epa.gov>  
**Cc:** Daniels, Rhys G. <daniels@khlaw.com>  
**Subject:** RE: **Ex. 4 CBI**

Hi Jeff –

Checking in again - thanks

---

**From:** Berger, Tom C.  
**Sent:** Friday, March 6, 2020 1:33 PM  
**To:** Bauer, Jeff <Bauer.Jeff@epa.gov>  
**Cc:** Daniels, Rhys G. <daniels@khlaw.com>  
**Subject:** RE: **Ex. 4 CBI**

Hi Jeff –

The submitter is quite anxious – can we touch base next week?

Thanks much - Tom

---

**From:** Berger, Tom C.  
**Sent:** Tuesday, February 25, 2020 9:08 AM  
**To:** Bauer, Jeff <Bauer.Jeff@epa.gov>  
**Cc:** Daniels, Rhys G. <daniels@khlaw.com>  
**Subject:** RE: **Ex. 4 CBI**

Hi Jeff –

Just checking in on this – thanks - Tom



---

**From:** Berger, Tom C.  
**Sent:** Thursday, February 20, 2020 12:18 PM  
**To:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>  
**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>  
**Subject:** RE: **Ex. 4 CBI**

Hi Jeff –

I hope that all is well.

Per our discussions, the submitter has modified the questions to focus on toxicity/risk issues and submitted them via CDX yesterday. Can we start looking at conference call dates the week of March 9?

Thanks and best regards,  
Tom

Thomas C. Berger  
Partner  
tel: 202.434.4285 | fax: 202.434.4646 | [berger@khlaw.com](mailto:berger@khlaw.com)  
1001 G Street, N.W., Suite 500 West | Washington, D.C. 20001

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**From:** Berger, Tom C.  
**Sent:** Wednesday, January 29, 2020 11:41 AM  
**To:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>  
**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>  
**Subject:** RE: **Ex. 4 CBI**

Hi Jeff –

Apologies we keep playing phone tag – can we discuss how to convert the below questions into questions that would be acceptable to RAD so we can schedule a call with you and RAD? Your voicemail suggested the below are more legal/regulatory than risk-based questions. We still need the below questions answered – perhaps we tee up the more scientific ones for RAD then have the call to address both types of questions. The submitter is under growing commercial pressure.

Thanks much again - Tom

---

**From:** Berger, Tom C.  
**Sent:** Monday, January 20, 2020 3:50 PM  
**To:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>  
**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>  
**Subject:** RE: **Ex. 4 CBI**

Hi Jeff –

Apologies that we could not connect last week. Let's try to touch base tomorrow (Tuesday) if possible to discuss how to move this forward.

Thanks again – Tom

Thomas C. Berger

Partner

tel: 202.434.4285 | fax: 202.434.4646 | [berger@khlaw.com](mailto:berger@khlaw.com)

1001 G Street, N.W., Suite 500 West | Washington, D.C. 20001

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**From:** Berger, Tom C.

**Sent:** Monday, January 13, 2020 2:50 PM

**To:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>

**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>

**Subject:** RE: **Ex. 4 CBI**

**Importance:** High

Hi Jeff –

Following is the list of questions we are considering submitting through CDX. Please let me know if these look ok.

Thanks again and best regards,

Tom

\* \* \*

*(1) Based on review of the submitted physical-chemical properties test data, does EPA now agree that use **Ex. 4 CBI** as described in the PMN poses no unreasonable risk of injury and so plans to revoke the consent order?*

*(2) If so, what is the process for revoking the current consent order? Does the submitter now need to request that EPA revoke the order, or will EPA itself initiate revocation? What is the expected timing for revocation? How would EPA communicate such revocation?*

*(3) How would revocation of the consent order impact the final SNUR for the subject substance?*

*(4) Would a SNUN be a more expedient approach?*

\* \* \*

---

**From:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>  
**Sent:** Wednesday, January 8, 2020 8:56 AM  
**To:** Berger, Tom C. <[Berger@khlaw.com](mailto:Berger@khlaw.com)>  
**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>  
**Subject:** RE: **Ex. 4 CBI**

Tom, I am expecting information from the engineer today or tomorrow on the **Ex. 4 CBI** test, I left you a message. There is a new procedure for us to set up meeting with RAD. I am to have the submitter send in a list of questions for RAD, they will assign someone up there as a Lead person who has two weeks and will set a date for when we can have a meeting. This may be our best route to other than just me bugging them to get things done. There were a series of emails on this case last week but now everyone is back from the holidays I am trying to get this case moving again.

Jeff Bauer - Program Manager  
United States Environmental Protection Agency (USEPA)  
Office of Pollution Prevention and Toxics (OPPT)  
New Chemicals Program (7405M)  
<http://www.epa.gov/oppt/newchems/>

EPA East Building, room 4133M  
1201 Constitution Ave., NW  
Washington, DC 20004  
Phone: 202-564-9042, Fax: 202-564-9490

---

**From:** Berger, Tom C. <[Berger@khlaw.com](mailto:Berger@khlaw.com)>  
**Sent:** Tuesday, January 07, 2020 4:16 PM  
**To:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>  
**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>  
**Subject:** RE: **Ex. 4 CBI**

Hi Jeff –

I hope you had a great holiday! The client was wondering if we could have a conference call on this, this week or next. Please advise.

Thanks much – Tom

Thomas C. Berger  
Partner  
tel: 202.434.4285 | fax: 202.434.4646 | [berger@khlaw.com](mailto:berger@khlaw.com)  
1001 G Street, N.W., Suite 500 West | Washington, D.C. 20001

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**From:** Berger, Tom C.  
**Sent:** Tuesday, December 10, 2019 2:10 PM  
**To:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>  
**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>  
**Subject:** RE: **Ex. 4 CBI**

Hi Jeff –

Just checking back in – thanks - Tom

---

**From:** Berger, Tom C.  
**Sent:** Thursday, December 5, 2019 9:46 AM  
**To:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>  
**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>  
**Subject:** RE: **Ex. 4 CBI**

Hi Jeff –

When we spoke before Thanksgiving (I hope you had a great one!) you indicated that the reports were being reviewed and that I should reach out to you in early December.

Is there any update?

Thanks much and best regards – Tom

Thomas C. Berger  
Partner  
tel: 202.434.4285 | fax: 202.434.4646 | [berger@khlaw.com](mailto:berger@khlaw.com)  
1001 G Street, N.W., Suite 500 West | Washington, D.C. 20001

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**From:** Berger, Tom C.  
**Sent:** Monday, November 18, 2019 1:17 PM  
**To:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>  
**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>  
**Subject:** RE: **Ex. 4 CBI**

Hi Jeff –

The PMN submitter asked me to reach out to you to see if we can schedule a conference call (including EPA, K&H, and the submitter) on this case re status and pathforward.

Thanks - Tom

---

**From:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>  
**Sent:** Friday, March 29, 2019 5:43 PM  
**To:** Berger, Tom C. <[Berger@khlaw.com](mailto:Berger@khlaw.com)>; Schweer, Greg <[Schweer.Greg@epa.gov](mailto:Schweer.Greg@epa.gov)>  
**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>  
**Subject:** RE: **Ex. 4 CBI**

Tom,  
I set the meeting up for Wednesday April 3, at 11 am. RAD has accepted the invitation for that time.

Jeff Bauer - Program Manager  
United States Environmental Protection Agency (USEPA)  
Office of Pollution Prevention and Toxics (OPPT)  
New Chemicals Program (7405M)  
<http://www.epa.gov/oppt/newchems/>

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1201 Constitution Ave., NW  
Washington, DC 20004  
Phone: 202-564-9042, Fax: 202-564-9490

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**From:** Bauer, Jeff  
**Sent:** Tuesday, March 26, 2019 11:37 AM  
**To:** 'Berger, Tom C.' <[Berger@khlaw.com](mailto:Berger@khlaw.com)>; Schweer, Greg <[Schweer.Greg@epa.gov](mailto:Schweer.Greg@epa.gov)>  
**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>  
**Subject:** RE: **Ex. 4 CBI**

Tom, I left you a voice message, I am seeing what time it best for RAD to be part of the call.

Jeff Bauer - Program Manager  
United States Environmental Protection Agency (USEPA)  
Office of Pollution Prevention and Toxics (OPPT)  
New Chemicals Program (7405M)  
<http://www.epa.gov/oppt/newchems/>

EPA East Building, room 4133M  
1201 Constitution Ave., NW  
Washington, DC 20004  
Phone: 202-564-9042, Fax: 202-564-9490

---

**From:** Berger, Tom C. <[Berger@khlaw.com](mailto:Berger@khlaw.com)>  
**Sent:** Tuesday, March 26, 2019 11:30 AM  
**To:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>; Schweer, Greg <[Schweer.Greg@epa.gov](mailto:Schweer.Greg@epa.gov)>  
**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>  
**Subject:** RE: **Ex. 4 CBI**

Hi folks –

Just thought I would check in with you on this.

Thanks again - Tom

---

**From:** Berger, Tom C.

**Sent:** Friday, March 22, 2019 2:12 PM

**To:** 'Bauer.jeff@Epa.gov' <Bauer.jeff@Epa.gov>; 'Schweer, Greg' <Schweer.Greg@epa.gov>

**Cc:** Daniels, Rhys G. <daniels@khlaw.com>

**Subject:** **Ex. 4 CBI**

Hi folks –

I hope you are doing well. Jeff – this is the PMN case that my colleague, Dr. Rhys Daniels, spoke with you about earlier this week.

The issue is development of data needed to amend the existing section 5(e) order for this substance to add an additional use, and EPA approval of protocols for same. Would the Agency be available for a short conference call on this on one of the following days?:

- March 27 (except 12-2 ET)
- April 2
- April 3
- April 4

This is becoming more urgent from a commercial standpoint.

Thanks much - Tom

Thomas C. Berger

Partner

tel: 202.434.4285 | fax: 202.434.4646 | [berger@khlaw.com](mailto:berger@khlaw.com)

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Message

---

**From:** Sullivan, Andrew [sullivan.andrew@epa.gov]  
**Sent:** 5/6/2020 7:54:07 PM  
**To:** Price, Amanda [price@khlaw.com]  
**CC:** Schweer, Greg [Schweer.Greg@epa.gov]; Edelstein, Rebecca [Edelstein.Rebecca@epa.gov]; Moss, Kenneth [Moss.Kenneth@epa.gov]; Yan, James [Yan.James@epa.gov]; Berger, Tom C. [Berger@khlaw.com]  
**Subject:** RE: Agreement to authorize transmittal of TSCA CBI via Outlook email with designated Agency representatives during the modified working conditions due to COVID-19

Great Amanda, Thanks for confirming.

Best,

Andrew (Drew) Sullivan | Program Manager  
New Chemicals Management Branch  
Chemical Control Division  
U.S. EPA Office of Pollution Prevention and Toxics  
Phone: 202-564-0605  
Fax: 202-564-9490  
*DO NOT SEND CBI TO THIS EMAIL*

---

**From:** Price, Amanda <price@khlaw.com>  
**Sent:** Wednesday, May 6, 2020 3:41 PM  
**To:** Sullivan, Andrew <sullivan.andrew@epa.gov>  
**Cc:** Schweer, Greg <Schweer.Greg@epa.gov>; Edelstein, Rebecca <Edelstein.Rebecca@epa.gov>; Moss, Kenneth <Moss.Kenneth@epa.gov>; Yan, James <Yan.James@epa.gov>; Berger, Tom C. <Berger@khlaw.com>  
**Subject:** RE: Agreement to authorize transmittal of TSCA CBI via Outlook email with designated Agency representatives during the modified working conditions due to COVID-19

Dear Drew,

We received the two reports and are able to open them.

Thank you,

Amanda (Mandy) C. Price  
Scientific Assistant  
**KELLER AND HECKMAN LLP**  
tel: +1 202.434.4236 | fax: +1 202.434.4646 | [Price@khlaw.com](mailto:Price@khlaw.com)  
1001 G Street NW, Suite 500 West | Washington, DC 20001



---

**From:** Sullivan, Andrew <sullivan.andrew@epa.gov>

**Sent:** Wednesday, May 6, 2020 2:05 PM

**To:** Price, Amanda <price@khlaw.com>

**Cc:** Schweer, Greg <Schweer.Greg@epa.gov>; Edelstein, Rebecca <Edelstein.Rebecca@epa.gov>; Moss, Kenneth <Moss.Kenneth@epa.gov>; Yan, James <Yan.James@epa.gov>; Berger, Tom C. <Berger@khlaw.com>; Sullivan, Andrew <sullivan.andrew@epa.gov>

**Subject:** [Not Virus Scanned] RE: Agreement to authorize transmittal of TSCA CBI via Outlook email with designated Agency representatives during the modified working conditions due to COVID-19

Hello Amanda and Tom,

Thank you for returning the signed authorization form. I confirmed that Tom is listed as a technical contact on your cases and have attached the password protected Third Party Sanitized Reports you requested.

Please reply that you've received them and have been able to access the reports. I will send you the passwords to access these files in a separate email.

Best,

Andrew (Drew) Sullivan | Program Manager  
New Chemicals Management Branch  
Chemical Control Division  
U.S. EPA Office of Pollution Prevention and Toxics  
Phone: 202-564-0605  
Fax: 202-564-9490  
DO NOT SEND CBI TO THIS EMAIL

---

**From:** Price, Amanda <price@khlaw.com>

**Sent:** Wednesday, May 6, 2020 1:36 PM

**To:** Sullivan, Andrew <sullivan.andrew@epa.gov>

**Cc:** Schweer, Greg <Schweer.Greg@epa.gov>; Edelstein, Rebecca <Edelstein.Rebecca@epa.gov>; Moss, Kenneth <Moss.Kenneth@epa.gov>; Yan, James <Yan.James@epa.gov>; Berger, Tom C. <Berger@khlaw.com>

**Subject:** RE: Agreement to authorize transmittal of TSCA CBI via Outlook email with designated Agency representatives during the modified working conditions due to COVID-19

Dear Drew,

Attached is the authorization form you requested. We look forward to receiving the reports.

Best regards,

Amanda (Mandy) C. Price  
Scientific Assistant  
**KELLER AND HECKMAN LLP**  
tel: +1 202.434.4236 | fax: +1 202.434.4646 | [Price@khlaw.com](mailto:Price@khlaw.com)  
1001 G Street NW, Suite 500 West | Washington, DC 20001



---

**From:** Sullivan, Andrew <sullivan.andrew@epa.gov>  
**Sent:** Wednesday, May 6, 2020 8:53 AM  
**To:** Price, Amanda <price@khlaw.com>  
**Cc:** Schweer, Greg <Schweer.Greg@epa.gov>; Edelstein, Rebecca <Edelstein.Rebecca@epa.gov>; Moss, Kenneth <Moss.Kenneth@epa.gov>; Yan, James <Yan.James@epa.gov>; Sullivan, Andrew <sullivan.andrew@epa.gov>  
**Subject:** FW: Agreement to authorize transmittal of TSCA CBI via Outlook email with designated Agency representatives during the modified working conditions due to COVID-19

Good Morning Amanda,

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Best,

Andrew (Drew) Sullivan | Program Manager  
New Chemicals Management Branch  
Chemical Control Division  
U.S. EPA Office of Pollution Prevention and Toxics  
Phone: 202-564-0605  
Fax: 202-564-9490  
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Andrew (Drew) Sullivan | Program Manager  
New Chemicals Management Branch  
Chemical Control Division  
U.S. EPA Office of Pollution Prevention and Toxics  
Phone: 202-564-0605  
Fax: 202-564-9490  
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Message

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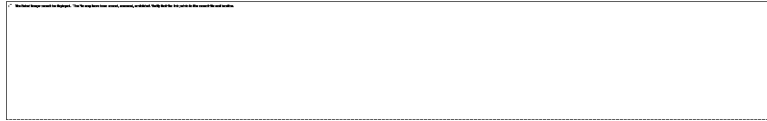
**From:** Price, Amanda [price@khlaw.com]  
**Sent:** 5/6/2020 7:41:09 PM  
**To:** Sullivan, Andrew [sullivan.andrew@epa.gov]  
**CC:** Schweer, Greg [Schweer.Greg@epa.gov]; Edelstein, Rebecca [Edelstein.Rebecca@epa.gov]; Moss, Kenneth [Moss.Kenneth@epa.gov]; Yan, James [Yan.James@epa.gov]; Berger, Tom C. [Berger@khlaw.com]  
**Subject:** RE: Agreement to authorize transmittal of TSCA CBI via Outlook email with designated Agency representatives during the modified working conditions due to COVID-19  
**Attachments:** ATT00001.txt

Dear Drew,

We received the two reports and are able to open them.

Thank you,

Amanda (Mandy) C. Price  
Scientific Assistant  
**KELLER AND HECKMAN LLP**  
tel: +1 202.434.4236 | fax: +1 202.434.4646 | Price@khlaw.com  
1001 G Street NW, Suite 500 West | Washington, DC 20001



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**From:** Sullivan, Andrew <sullivan.andrew@epa.gov>  
**Sent:** Wednesday, May 6, 2020 2:05 PM  
**To:** Price, Amanda <price@khlaw.com>  
**Cc:** Schweer, Greg <Schweer.Greg@epa.gov>; Edelstein, Rebecca <Edelstein.Rebecca@epa.gov>; Moss, Kenneth <Moss.Kenneth@epa.gov>; Yan, James <Yan.James@epa.gov>; Berger, Tom C. <Berger@khlaw.com>; Sullivan, Andrew <sullivan.andrew@epa.gov>  
**Subject:** [Not Virus Scanned] RE: Agreement to authorize transmittal of TSCA CBI via Outlook email with designated Agency representatives during the modified working conditions due to COVID-19

Hello Amanda and Tom,

Thank you for returning the signed authorization form. I confirmed that Tom is listed as a technical contact on your cases and have attached the password protected Third Party Sanitized Reports you requested.

Please reply that you've received them and have been able to access the reports. I will send you the passwords to access these files in a separate email.

Best,

Andrew (Drew) Sullivan | Program Manager

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**Sent:** Wednesday, May 6, 2020 1:36 PM  
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**Cc:** Schweer, Greg <[Schweer.Greg@epa.gov](mailto:Schweer.Greg@epa.gov)>; Edelstein, Rebecca <[Edelstein.Rebecca@epa.gov](mailto:Edelstein.Rebecca@epa.gov)>; Moss, Kenneth <[Moss.Kenneth@epa.gov](mailto:Moss.Kenneth@epa.gov)>; Yan, James <[Yan.James@epa.gov](mailto:Yan.James@epa.gov)>; Berger, Tom C. <[Berger@khlaw.com](mailto:Berger@khlaw.com)>  
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New Chemicals Management Branch  
Chemical Control Division  
U.S. EPA Office of Pollution Prevention and Toxics  
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Message

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**Sent:** 5/6/2020 6:05:25 PM  
**To:** Price, Amanda [price@khlaw.com]  
**CC:** Schweer, Greg [Schweer.Greg@epa.gov]; Edelstein, Rebecca [Edelstein.Rebecca@epa.gov]; Moss, Kenneth [Moss.Kenneth@epa.gov]; Yan, James [Yan.James@epa.gov]; Berger, Tom C. [Berger@khlaw.com]; Sullivan, Andrew [sullivan.andrew@epa.gov]  
**Subject:** RE: Agreement to authorize transmittal of TSCA CBI via Outlook email with designated Agency representatives during the modified working conditions due to COVID-19  
**Attachments:** L-XX-XXX0\_ENG Report\_04-14-20 Marked\_Redacted.pdf; L-XX-XXX9\_ENG Report\_04-14-20 Redacted.pdf

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New Chemicals Management Branch  
Chemical Control Division  
U.S. EPA Office of Pollution Prevention and Toxics  
Phone: 202-564-0605  
Fax: 202-564-9490  
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Message

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**Sent:** 5/6/2020 5:35:39 PM  
**To:** Sullivan, Andrew [sullivan.andrew@epa.gov]  
**CC:** Schweer, Greg [Schweer.Greg@epa.gov]; Edelstein, Rebecca [Edelstein.Rebecca@epa.gov]; Moss, Kenneth [Moss.Kenneth@epa.gov]; Yan, James [Yan.James@epa.gov]; Berger, Tom C. [Berger@khlaw.com]  
**Subject:** RE: Agreement to authorize transmittal of TSCA CBI via Outlook email with designated Agency representatives during the modified working conditions due to COVID-19  
**Attachments:** ATT00001.txt; Authorization Form for CBI transmittal by e-mail revised 4-20 (002).pdf

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Best regards,

Amanda (Mandy) C. Price  
Scientific Assistant  
**KELLER AND HECKMAN LLP**  
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Greg Schweer at (202) 564-8469 or the EPA Program Manager assigned to the case, Drew Sullivan, at the number below.

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Chemical Control Division  
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Phone: 202-564-0605  
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*DO NOT SEND CBI TO THIS EMAIL*

**Agreement to authorize transmittal of TSCA Confidential Business Information (CBI) via Outlook email by designated Agency representatives during the period of EPA telework due to COVID-19**

Documents concerning: L-20-0099 and L-20-0100

**COMPANY** authorizes EPA to transmit documents related to the above referenced TSCA submission, including information claimed as CBI, to **COMPANY** (or its technical contact listed on the PMN form) through EPA's Outlook email system. This authorization applies only during those periods where EPA staff working on PMN-XX-XXX are teleworking due to COVID-19 concerns and may be withdrawn at any time. Nothing in this authorization diminishes or otherwise limits **COMPANY'S** protections under TSCA to assert information as CBI, or otherwise authorizes the release of any information claimed as CBI without exhausting all provisions of TSCA protecting the release of such information. I have the authority to sign this on behalf of **COMPANY**



Signature of authorized person: \_\_\_\_\_

Name of authorized person printed or typed: Thomas C. Berger

Title: Partner

Email address: berger@khlaw.com

Telephone number Ex. 6 Personal Privacy (PP) \_\_\_\_\_

**COMPANY** Keller and Heckman LLP

Message

---

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**Sent:** 5/6/2020 12:53:06 PM  
**To:** Price, Amanda [price@khlaw.com]  
**CC:** Schweer, Greg [Schweer.Greg@epa.gov]; Edelstein, Rebecca [Edelstein.Rebecca@epa.gov]; Moss, Kenneth [Moss.Kenneth@epa.gov]; Yan, James [Yan.James@epa.gov]; Sullivan, Andrew [sullivan.andrew@epa.gov]  
**Subject:** FW: Agreement to authorize transmittal of TSCA CBI via Outlook email with designated Agency representatives during the modified working conditions due to COVID-19  
**Attachments:** Authorization Form for CBI transmittal by e-mail revised 4-20.docx

Good Morning Amanda,

I didn't received the authorization form from you yet so I am forwarding my earlier request for you to fill out and sign the authorization form allowing EPA to email you third party redacted reports. Thank you.

Best,

Andrew (Drew) Sullivan | Program Manager  
New Chemicals Management Branch  
Chemical Control Division  
U.S. EPA Office of Pollution Prevention and Toxics  
Phone: 202-564-0605  
Fax: 202-564-9490  
*DO NOT SEND CBI TO THIS EMAIL*

---

**From:** Sullivan, Andrew <sullivan.andrew@epa.gov>  
**Sent:** Wednesday, April 29, 2020 3:20 PM  
**To:** Price, Amanda <price@khlaw.com>  
**Cc:** Schweer, Greg <Schweer.Greg@epa.gov>; Edelstein, Rebecca <Edelstein.Rebecca@epa.gov>; Moss, Kenneth <Moss.Kenneth@epa.gov>; Yan, James <Yan.James@epa.gov>; Sullivan, Andrew <sullivan.andrew@epa.gov>  
**Subject:** Agreement to authorize transmittal of TSCA CBI via Outlook email with designated Agency representatives during the modified working conditions due to COVID-19

Hello Amanda,

As we discussed, please add the 2 LVE case numbers that I am working on with you to the attached authorization form, sign it, and email it back (reply all). Then I can email you the redacted reports we discussed earlier. Here is the formal authorization request. Thank you.

In an effort to encourage social distancing and help reduce community spread of COVID-19, most EPA staff have been authorized to telework until at least April 30, 2020. With a majority of EPA staff now teleworking from remote sites, some minor changes to the normal TSCA section 5 review processes, including the TSCA section 5(a)(3) determination processes, are required. Specifically, the normal process by which section 5(a)(3)(C) determination documents and section 5(e) orders are transmitted to submitters, because they contain information claimed as CBI, are hard copies submitted by the mail or courier services and via fax machines. These methods of delivery are not available from remote sites and therefore other means of transmitting this information must be utilized.

Given this extraordinary situation, and to avoid delay in addressing TSCA section 5 requirements, the Agency is offering an option to allowed affected persons to agree to allow EPA to transmit these materials via normal non-encrypted Outlook email. If you agree to this, the Agency will transmit these documents to you via email during the period in which a majority of EPA staff is teleworking. In the absence of this agreement EPA may need to extend the review period for your submission or issue a unilateral order under Section 5(e). Please note that EPA is not requiring companies to agree to transmission via email. Rather this communication explains the constraints we are acting under, and the delays that would result in the absence of email transmission. Companies are free to choose as appropriate.

Also, please note that agreeing to this process is a limited waiver of the TSCA CBI procedural protections, which generally restricts the transmission of CBI over a non-encrypted email system. That said, EPA's email system is compliant with all applicable Federal government information security provisions, including the Federal Information Security Management Act, and EPA's email systems meet the level of protection required for storing and transmitting CBI. Furthermore, your agreement will not constitute a waiver of substantive CBI protections, meaning that the information transmitted and claimed as confidential will only be disclosed consistent with TSCA, other applicable laws, and associated implementing regulations.

If you wish to grant EPA a limited waiver to transmit the materials via EPA's email system during the period in which a majority of EPA staff is teleworking, please have your authorized representative complete, sign, and return the attached to Greg Schweer ([Schweer.greg@epa.gov](mailto:Schweer.greg@epa.gov)) as well as to any EPA staff who were cc'd on the email sent to you. Also please follow the instructions below for the transmittal of information subject to this agreement. If you have any questions about this communication or the described process, please contact Greg Schweer at (202) 564-8469 or the EPA Program Manager assigned to the case, Drew Sullivan, at the number below.

Andrew (Drew) Sullivan | Program Manager  
New Chemicals Management Branch  
Chemical Control Division  
U.S. EPA Office of Pollution Prevention and Toxics  
Phone: 202-564-0605  
Fax: 202-564-9490  
*DO NOT SEND CBI TO THIS EMAIL*

**Agreement to authorize transmittal of TSCA Confidential Business Information (CBI) via Outlook email by designated Agency representatives during the period of EPA telework due to COVID-19**

Documents concerning: PMN-XX-XXX

**COMPANY** authorizes EPA to transmit documents related to the above referenced TSCA submission, including information claimed as CBI, to **COMPANY** (or its technical contact listed on the PMN form) through EPA's Outlook email system. This authorization applies only during those periods where EPA staff working on PMN-XX-XXX are teleworking due to COVID-19 concerns and may be withdrawn at any time. Nothing in this authorization diminishes or otherwise limits **COMPANY'S** protections under TSCA to assert information as CBI, or otherwise authorizes the release of any information claimed as CBI without exhausting all provisions of TSCA protecting the release of such information. I have the authority to sign this on behalf of **COMPANY**

Signature of authorized person: \_\_\_\_\_

Name of authorized person printed or typed: \_\_\_\_\_

Title: \_\_\_\_\_

Email address: \_\_\_\_\_

Telephone number: \_\_\_\_\_

**COMPANY** \_\_\_\_\_



Message

---

**From:** Berger, Tom C. [Berger@khlaw.com]  
**Sent:** 5/5/2020 3:55:46 PM  
**To:** Bauer, Jeff [Bauer.Jeff@epa.gov]  
**CC:** Price, Amanda [price@khlaw.com]; Schweer, Greg [Schweer.Greg@epa.gov]; Daniels, Rhys G. [daniels@khlaw.com]  
**Subject:** RE: **Ex. 4 CBI**

Hi Jeff – Just checking in on this – thanks - Tom

---

**From:** Berger, Tom C.  
**Sent:** Wednesday, April 29, 2020 11:12 AM  
**To:** Bauer, Jeff <Bauer.Jeff@epa.gov>  
**Cc:** Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>  
**Subject:** RE: **Ex. 4 CBI**

Hi Jeff –

I just thought I would check in on this and see if the Agency needs any additional information.

Thanks again and best regards,  
Tom

Thomas C. Berger  
Partner  
tel: 202.434.4285 | fax: 202.434.4646 | [berger@khlaw.com](mailto:berger@khlaw.com)  
1001 G Street, N.W., Suite 500 West | Washington, D.C. 20001

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**From:** Berger, Tom C.  
**Sent:** Thursday, April 23, 2020 7:13 PM  
**To:** 'Bauer, Jeff' <Bauer.Jeff@epa.gov>  
**Cc:** Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>  
**Subject:** RE: **Ex. 4 CBI**

Jeff - thanks much.

Your recent voicemail and follow-up email indicated that the EPA Chemist has evaluated the **Ex. 4 CBI** study" on **Ex. 4 CBI** **Ex. 4 CBI** but that the reviewer did have a few questions and comments:

**Ex. 4 CBI**

# Ex. 4 CBI

To specifically answer the Chemist's questions:

# Ex. 4 CBI

# Ex. 4 CBI

\* \* \*

We trust that you find this information useful in resolved all outstanding issues. As always, if you have any questions please do not hesitate to contact us.

Best regards,  
Tom

Thomas C. Berger  
Partner  
tel: 202.434.4285 | fax: 202.434.4646 | [berger@khlaw.com](mailto:berger@khlaw.com)  
1001 G Street, N.W., Suite 500 West | Washington, D.C. 20001

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**From:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>  
**Sent:** Tuesday, April 21, 2020 5:17 PM  
**To:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>; Berger, Tom C. <[Berger@khlaw.com](mailto:Berger@khlaw.com)>  
**Cc:** Price, Amanda <[price@khlaw.com](mailto:price@khlaw.com)>; Schweer, Greg <[Schweer.Greg@epa.gov](mailto:Schweer.Greg@epa.gov)>  
**Subject:** RE: Ex. 4 CBI

I am moving forward with the review based on the information I have on the two studies, I wanted to share with you her comments on the test. Ex. 4 CBI

Ex. 4 CBI RAD has the information and I am trying to get them to do the risk assessment based on Ex. 4 CBI

Jeff Bauer - Program Manager  
United States Environmental Protection Agency (USEPA)  
Office of Pollution Prevention and Toxics (OPPT)  
New Chemicals Program (7405M)  
<http://www.epa.gov/oppt/newchemicals/>

EPA East Building, room 4133M  
1201 Constitution Ave., NW  
Washington, DC 20004  
Phone: 202-564-9042, Fax: 202-564-9490

---

**From:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>  
**Sent:** Tuesday, April 21, 2020 4:58 PM  
**To:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>; Berger, Tom C. <[Berger@khlaw.com](mailto:Berger@khlaw.com)>  
**Cc:** Price, Amanda <[price@khlaw.com](mailto:price@khlaw.com)>; Schweer, Greg <[Schweer.Greg@epa.gov](mailto:Schweer.Greg@epa.gov)>  
**Subject:** RE: Ex. 4 CBI

Jeff,

As always, we hope that all is well.

Per your recent voicemail and follow-up email concerning the Ex. 4 CBI case, we understand that the chemist has two questions concerning Ex. 4 CBI

**Ex. 4 CBI**

Thanks in advance for your response.

Rhys G. Daniels, Ph.D.  
Staff Scientist

tel: +1 202.434.4270 | fax: +1 202.434.4646 | [daniels@khlaw.com](mailto:daniels@khlaw.com)  
1001 G Street NW, Suite 500 West | Washington, DC 20001

**From:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>  
**Sent:** Thursday, April 16, 2020 1:02 PM  
**To:** Berger, Tom C. <[Berger@khlaw.com](mailto:Berger@khlaw.com)>  
**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>; Price, Amanda <[price@khlaw.com](mailto:price@khlaw.com)>; Schweer, Greg <[Schweer.Greg@epa.gov](mailto:Schweer.Greg@epa.gov)>  
**Subject:** RE: **Ex. 4 CBI**

Tom,

The chemist sent me a memo **Ex. 4 CBI** and they had two questions, I called and left you a message today **Ex. 4 CBI**. I sent RAD a request last week to update the HH assessment **Ex. 4 CBI** **Ex. 4 CBI** as in my April 4, 2020 email to you. I have two emails into RAD on this case and will try an update you again in a week or so. I requested RAD set up a date with me to have a meeting to discuss how to proceed with this PMN.

Thanks  
Jeff

Jeff Bauer - Program Manager  
United States Environmental Protection Agency (USEPA)  
Office of Pollution Prevention and Toxics (OPPT)  
New Chemicals Program (7405M)  
<http://www.epa.gov/oppt/newchems/>

EPA East Building, room 4133M  
1201 Constitution Ave., NW  
Washington, DC 20004  
Phone: 202-564-9042, Fax: 202-564-9490

**From:** Berger, Tom C. <[Berger@khlaw.com](mailto:Berger@khlaw.com)>  
**Sent:** Thursday, April 16, 2020 12:28 PM  
**To:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>  
**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>; Price, Amanda <[price@khlaw.com](mailto:price@khlaw.com)>; Schweer, Greg <[Schweer.Greg@epa.gov](mailto:Schweer.Greg@epa.gov)>  
**Subject:** RE: **Ex. 4 CBI**

Hi Jeff –

I hope that all is well.

Just checking in re status update. A non-CBI-containing email from you would probably be the best (if needed at some later time we can use EPA's new CBI via email authorization form if the submitter agrees).

Thanks again – Tom

---

**From:** Berger, Tom C.  
**Sent:** Wednesday, April 8, 2020 11:06 AM  
**To:** Bauer, Jeff <Bauer.Jeff@epa.gov>; Schweer, Greg <Schweer.Greg@epa.gov>  
**Cc:** Daniels, Rhys G. <daniels@khlaw.com>; Price, Amanda <price@khlaw.com>  
**Subject:** RE: **Ex. 4 CBI**

Jeff – thanks much for the update. Hope you and all at EPA are staying safe.

Tom

---

**From:** Bauer, Jeff <Bauer.Jeff@epa.gov>  
**Sent:** Wednesday, April 8, 2020 11:03 AM  
**To:** Berger, Tom C. <Berger@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>  
**Cc:** Daniels, Rhys G. <daniels@khlaw.com>; Price, Amanda <price@khlaw.com>  
**Subject:** RE: **Ex. 4 CBI**

Tom,

# Ex. 4 CBI

I will follow up with you next wed with a status update.

Jeff Bauer - Program Manager  
United States Environmental Protection Agency (USEPA)  
Office of Pollution Prevention and Toxics (OPPT)  
New Chemicals Program (7405M)  
<http://www.epa.gov/oppt/newchemicals/>

EPA East Building, room 4133M  
1201 Constitution Ave., NW  
Washington, DC 20004  
Phone: 202-564-9042, Fax: 202-564-9490

---

**From:** Berger, Tom C. <Berger@khlaw.com>  
**Sent:** Wednesday, April 08, 2020 10:48 AM  
**To:** Schweer, Greg <Schweer.Greg@epa.gov>  
**Cc:** Daniels, Rhys G. <daniels@khlaw.com>; Bauer, Jeff <Bauer.Jeff@epa.gov>; Price, Amanda <price@khlaw.com>  
**Subject:** RE: **Ex. 4 CBI**

Hi Greg –

I was just going through my to-do list and thought I would circle back on these two cases. I hope everyone is hanging in there.

Thanks again – Tom

---

**From:** Berger, Tom C.  
**Sent:** Monday, March 30, 2020 3:46 PM  
**To:** Schweer, Greg <Schweer.Greg@epa.gov>  
**Cc:** Daniels, Rhys G. <daniels@khlaw.com>; Bauer, Jeff <Bauer.Jeff@epa.gov>; Price, Amanda <price@khlaw.com>  
**Subject:** RE: **Ex. 4 CBI**

Greg / all – completely understood – thank you so much.

Tom

---

**From:** Schweer, Greg <Schweer.Greg@epa.gov>  
**Sent:** Monday, March 30, 2020 3:42 PM  
**To:** Berger, Tom C. <Berger@khlaw.com>  
**Cc:** Daniels, Rhys G. <daniels@khlaw.com>; Bauer, Jeff <Bauer.Jeff@epa.gov>  
**Subject:** RE: **Ex. 4 CBI**

Hi Tom.

I am not ignoring you. I did check with Jeff Bauer early last week on this case. He filled me in on the requests he had made of RAD to review submitted test data and your request for a meeting. However, believe it or not, we have been having issues reliably being able to access our CBI-secure LAN. This hampers our ability to efficiently complete work. I will check on the status of your case as soon as I can.

---

**From:** Berger, Tom C. <Berger@khlaw.com>  
**Sent:** Monday, March 30, 2020 11:51 AM  
**To:** Schweer, Greg <Schweer.Greg@epa.gov>  
**Cc:** Daniels, Rhys G. <daniels@khlaw.com>  
**Subject:** RE: **Ex. 4 CBI**

Hi Greg –

Hope all is well.

Just thought I would check in with you on the **Ex. 4 CBI** LVEA (Lauren Davis) and **Ex. 4 CBI** **Ex. 4 CBI** with Jeff Bauer.

Thanks all always - Tom

---

**From:** Berger, Tom C.  
**Sent:** Tuesday, March 24, 2020 11:12 AM  
**To:** Schweer, Greg <Schweer.Greg@epa.gov>  
**Cc:** Daniels, Rhys G. <daniels@khlaw.com>  
**Subject:** RE: **Ex. 4 CBI**

Greg – thanks so much as always. I also have an LVE with Lauren Davis **Ex. 4 CBI** held up in the process. Lauren has been responsive but the case has stalled (again, however, I understand the challenges you are facing).

These are my two "priority" cases.

Tom

---

**From:** Schweer, Greg <Schweer.Greg@epa.gov>  
**Sent:** Tuesday, March 24, 2020 11:07 AM  
**To:** Berger, Tom C. <Berger@khlaw.com>  
**Cc:** Daniels, Rhys G. <daniels@khlaw.com>  
**Subject:** Re: **Ex. 4 CBI**

Tom,

Yes, things are a bit crazy. I will check into the case status today or tomorrow.

Sent from my iPhone

On Mar 24, 2020, at 10:48 AM, Berger, Tom C. <Berger@khlaw.com> wrote:

Hi Greg –

Obviously things are crazy and I don't want to push Jeff too hard but no response from Jeff on this case for a month.

Hang in there....

Tom

---

**From:** Berger, Tom C.  
**Sent:** Monday, March 23, 2020 6:22 PM  
**To:** Bauer, Jeff <Bauer.Jeff@epa.gov>  
**Cc:** Daniels, Rhys G. <daniels@khlaw.com>  
**Subject:** RE: **Ex. 4 CBI**

Hi Jeff –

Apologies – just want to make sure you are getting these emails. Understand if there are delays.

Tom

---

**From:** Berger, Tom C.  
**Sent:** Thursday, March 19, 2020 5:22 PM  
**To:** Bauer, Jeff <Bauer.Jeff@epa.gov>  
**Cc:** Daniels, Rhys G. <daniels@khlaw.com>  
**Subject:** RE: **Ex. 4 CBI**

Hi Jeff – checking in again – thanks - Tom

---

**From:** Berger, Tom C.  
**Sent:** Monday, March 16, 2020 1:40 PM  
**To:** Bauer, Jeff <Bauer.Jeff@epa.gov>



**Cc:** Daniels, Rhys G. <daniels@khlaw.com>

**Subject:** RE: **Ex. 4 CBI**

Hi Jeff –

I know things are crazy but checking in again – thanks - Tom

---

**From:** Berger, Tom C.

**Sent:** Wednesday, March 11, 2020 3:43 PM

**To:** Bauer, Jeff <Bauer.Jeff@epa.gov>

**Cc:** Daniels, Rhys G. <daniels@khlaw.com>

**Subject:** RE: **Ex. 4 CBI**

Hi Jeff –

Checking in again - thanks

---

**From:** Berger, Tom C.

**Sent:** Friday, March 6, 2020 1:33 PM

**To:** Bauer, Jeff <Bauer.Jeff@epa.gov>

**Cc:** Daniels, Rhys G. <daniels@khlaw.com>

**Subject:** RE: **Ex. 4 CBI**

Hi Jeff –

The submitter is quite anxious – can we touch base next week?

Thanks much - Tom

---

**From:** Berger, Tom C.

**Sent:** Tuesday, February 25, 2020 9:08 AM

**To:** Bauer, Jeff <Bauer.Jeff@epa.gov>

**Cc:** Daniels, Rhys G. <daniels@khlaw.com>

**Subject:** RE: **Ex. 4 CBI**

Hi Jeff –

Just checking in on this – thanks - Tom

---

**From:** Berger, Tom C.

**Sent:** Thursday, February 20, 2020 12:18 PM

**To:** Bauer, Jeff <Bauer.Jeff@epa.gov>

**Cc:** Daniels, Rhys G. <daniels@khlaw.com>

**Subject:** RE: **Ex. 4 CBI**

Hi Jeff –

I hope that all is well.

Per our discussions, the submitter has modified the questions to focus on toxicity/risk issues and submitted them via CDX yesterday. Can we start looking at conference call dates the week of March 9?

Thanks and best regards,  
Tom

Thomas C. Berger  
Partner  
tel: 202.434.4285 | fax: 202.434.4646 | [berger@khlaw.com](mailto:berger@khlaw.com)  
1001 G Street, N.W., Suite 500 West | Washington, D.C. 20001

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**From:** Berger, Tom C.  
**Sent:** Wednesday, January 29, 2020 11:41 AM  
**To:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>  
**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>  
**Subject:** RE: **Ex. 4 CBI**

Hi Jeff –

Apologies we keep playing phone tag – can we discuss how to convert the below questions into questions that would be acceptable to RAD so we can schedule a call with you and RAD? Your voicemail suggested the below are more legal/regulatory than risk-based questions. We still need the below questions answered – perhaps we tee up the more scientific ones for RAD then have the call to address both types of questions. The submitter is under growing commercial pressure.

Thanks much again - Tom

---

**From:** Berger, Tom C.  
**Sent:** Monday, January 20, 2020 3:50 PM  
**To:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>  
**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>  
**Subject:** RE: **Ex. 4 CBI**

Hi Jeff –

Apologies that we could not connect last week. Let's try to touch base tomorrow (Tuesday) if possible to discuss how to move this forward.

Thanks again – Tom

Thomas C. Berger  
Partner  
tel: 202.434.4285 | fax: 202.434.4646 | [berger@khlaw.com](mailto:berger@khlaw.com)  
1001 G Street, N.W., Suite 500 West | Washington, D.C. 20001

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**From:** Berger, Tom C.  
**Sent:** Monday, January 13, 2020 2:50 PM  
**To:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>  
**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>  
**Subject:** RE: **Ex. 4 CBI**  
**Importance:** High

Hi Jeff –

Following is the list of questions we are considering submitting through CDX. Please let me know if these look ok.

Thanks again and best regards,  
Tom

\* \* \*

*(1) Based on review of the submitted physical-chemical properties test data, does EPA now agree that use **Ex. 4 CBI** as described in the PMN poses no unreasonable risk of injury and so plans to revoke the consent order?*

*(2) If so, what is the process for revoking the current consent order? Does the submitter now need to request that EPA revoke the order, or will EPA itself initiate revocation? What is the expected timing for revocation? How would EPA communicate such revocation?*

*(3) How would revocation of the consent order impact the final SNUR for the subject substance?*

*(4) Would a SNUN be a more expedient approach?*

\* \* \*

---

**From:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>  
**Sent:** Wednesday, January 8, 2020 8:56 AM  
**To:** Berger, Tom C. <[Berger@khlaw.com](mailto:Berger@khlaw.com)>  
**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>  
**Subject:** RE: **Ex. 4 CBI**

Tom, I am expecting information from the engineer today or tomorrow on the **Ex. 4 CBI** test. I left you a message. There is a new procedure for us to set up meeting with RAD. I am to have the submitter send in a list of questions for RAD, they will assign someone up there as a Lead person who has two weeks

and will set a date for when we can have a meeting. This may be our best route to other than just me bugging them to get things done. There were a series of emails on this case last week but now everyone is back from the holidays I am trying to get this case moving again.

Jeff Bauer - Program Manager  
United States Environmental Protection Agency (USEPA)  
Office of Pollution Prevention and Toxics (OPPT)  
New Chemicals Program (7405M)  
<http://www.epa.gov/oppt/newchemicals/>

EPA East Building, room 4133M  
1201 Constitution Ave., NW  
Washington, DC 20004  
Phone: 202-564-9042, Fax: 202-564-9490

---

**From:** Berger, Tom C. <[Berger@khlaw.com](mailto:Berger@khlaw.com)>  
**Sent:** Tuesday, January 07, 2020 4:16 PM  
**To:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>  
**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>  
**Subject:** RE: **Ex. 4 CBI**

Hi Jeff –

I hope you had a great holiday! The client was wondering if we could have a conference call on this, this week or next. Please advise.

Thanks much – Tom

Thomas C. Berger  
Partner  
tel: 202.434.4285 | fax: 202.434.4646 | [berger@khlaw.com](mailto:berger@khlaw.com)  
1001 G Street, N.W., Suite 500 West | Washington, D.C. 20001

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**From:** Berger, Tom C.  
**Sent:** Tuesday, December 10, 2019 2:10 PM  
**To:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>  
**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>  
**Subject:** RE: **Ex. 4 CBI**

Hi Jeff –

Just checking back in – thanks - Tom

---

**From:** Berger, Tom C.  
**Sent:** Thursday, December 5, 2019 9:46 AM  
**To:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>  
**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>  
**Subject:** RE: **Ex. 4 CBI**

Hi Jeff –

When we spoke before Thanksgiving (I hope you had a great one!) you indicated that the reports were being reviewed and that I should reach out to you in early December.

Is there any update?

Thanks much and best regards – Tom

Thomas C. Berger  
Partner  
tel: 202.434.4285 | fax: 202.434.4646 | [berger@khlaw.com](mailto:berger@khlaw.com)  
1001 G Street, N.W., Suite 500 West | Washington, D.C. 20001

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**From:** Berger, Tom C.  
**Sent:** Monday, November 18, 2019 1:17 PM  
**To:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>  
**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>  
**Subject:** RE: **Ex. 4 CBI**

Hi Jeff –

The PMN submitter asked me to reach out to you to see if we can schedule a conference call (including EPA, K&H, and the submitter) on this case re status and pathforward.

Thanks - Tom

---

**From:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>  
**Sent:** Friday, March 29, 2019 5:43 PM  
**To:** Berger, Tom C. <[Berger@khlaw.com](mailto:Berger@khlaw.com)>; Schweer, Greg <[Schweer.Greg@epa.gov](mailto:Schweer.Greg@epa.gov)>  
**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>  
**Subject:** RE: **Ex. 4 CBI**

Tom,

I set the meeting up for Wednesday April 3, at 11 am. RAD has accepted the invitation for that time.

Jeff Bauer - Program Manager  
United States Environmental Protection Agency (USEPA)  
Office of Pollution Prevention and Toxics (OPPT)  
New Chemicals Program (7405M)  
<http://www.epa.gov/oppt/newchemicals/>

EPA East Building, room 4133M  
1201 Constitution Ave., NW  
Washington, DC 20004  
Phone: 202-564-9042, Fax: 202-564-9490

---

**From:** Bauer, Jeff  
**Sent:** Tuesday, March 26, 2019 11:37 AM  
**To:** 'Berger, Tom C.' <[Berger@khlaw.com](mailto:Berger@khlaw.com)>; Schweer, Greg <[Schweer.Greg@epa.gov](mailto:Schweer.Greg@epa.gov)>  
**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>  
**Subject:** RE: **Ex. 4 CBI**

Tom, I left you a voice message, I am seeing what time it best for RAD to be part of the call.

Jeff Bauer - Program Manager  
United States Environmental Protection Agency (USEPA)  
Office of Pollution Prevention and Toxics (OPPT)  
New Chemicals Program (7405M)  
<http://www.epa.gov/oppt/newchemicals/>

EPA East Building, room 4133M  
1201 Constitution Ave., NW  
Washington, DC 20004  
Phone: 202-564-9042, Fax: 202-564-9490

---

**From:** Berger, Tom C. <[Berger@khlaw.com](mailto:Berger@khlaw.com)>  
**Sent:** Tuesday, March 26, 2019 11:30 AM  
**To:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>; Schweer, Greg <[Schweer.Greg@epa.gov](mailto:Schweer.Greg@epa.gov)>  
**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>  
**Subject:** RE: **Ex. 4 CBI**

Hi folks –

Just thought I would check in with you on this.

Thanks again - Tom

---

**From:** Berger, Tom C.  
**Sent:** Friday, March 22, 2019 2:12 PM  
**To:** 'Bauer.jeff@Epa.gov' <[Bauer.jeff@Epa.gov](mailto:Bauer.jeff@Epa.gov)>; 'Schweer, Greg' <[Schweer.Greg@epa.gov](mailto:Schweer.Greg@epa.gov)>  
**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>  
**Subject:** **Ex. 4 CBI**

Hi folks –

I hope you are doing well. Jeff – this is the PMN case that my colleague, Dr. Rhys Daniels, spoke with you about earlier this week.

The issue is development of data needed to amend the existing section 5(e) order for this substance to add an additional use, and EPA approval of protocols for same. Would the Agency be available for a short conference call on this on one of the following days?:

- March 27 (except 12-2 ET)
- April 2
- April 3
- April 4

This is becoming more urgent from a commercial standpoint.

Thanks much - Tom

Thomas C. Berger

Partner

tel: 202.434.4285 | fax: 202.434.4646 | [berger@khlaw.com](mailto:berger@khlaw.com)

1001 G Street, N.W., Suite 500 West | Washington, D.C. 20001

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Message

---

**From:** Sullivan, Andrew [sullivan.andrew@epa.gov]  
**Sent:** 4/29/2020 7:20:07 PM  
**To:** Price, Amanda [price@khlaw.com]  
**CC:** Schweer, Greg [Schweer.Greg@epa.gov]; Edelstein, Rebecca [Edelstein.Rebecca@epa.gov]; Moss, Kenneth [Moss.Kenneth@epa.gov]; Yan, James [Yan.James@epa.gov]; Sullivan, Andrew [sullivan.andrew@epa.gov]  
**Subject:** Agreement to authorize transmittal of TSCA CBI via Outlook email with designated Agency representatives during the modified working conditions due to COVID-19  
**Attachments:** Authorization Form for CBI transmittal by e-mail revised 4-20.docx

Hello Amanda,

As we discussed, please add the 2 LVE case numbers that I am working on with you to the attached authorization form, sign it, and email it back (reply all). Then I can email you the redacted reports we discussed earlier. Here is the formal authorization request. Thank you.

In an effort to encourage social distancing and help reduce community spread of COVID-19, most EPA staff have been authorized to telework until at least April 30, 2020. With a majority of EPA staff now teleworking from remote sites, some minor changes to the normal TSCA section 5 review processes, including the TSCA section 5(a)(3) determination processes, are required. Specifically, the normal process by which section 5(a)(3)(C) determination documents and section 5(e) orders are transmitted to submitters, because they contain information claimed as CBI, are hard copies submitted by the mail or courier services and via fax machines. These methods of delivery are not available from remote sites and therefore other means of transmitting this information must be utilized.

Given this extraordinary situation, and to avoid delay in addressing TSCA section 5 requirements, the Agency is offering an option to allowed affected persons to agree to allow EPA to transmit these materials via normal non-encrypted Outlook email. If you agree to this, the Agency will transmit these documents to you via email during the period in which a majority of EPA staff is teleworking. In the absence of this agreement EPA may need to extend the review period for your submission or issue a unilateral order under Section 5(e). Please note that EPA is not requiring companies to agree to transmission via email. Rather this communication explains the constraints we are acting under, and the delays that would result in the absence of email transmission. Companies are free to choose as appropriate.

Also, please note that agreeing to this process is a limited waiver of the TSCA CBI procedural protections, which generally restricts the transmission of CBI over a non-encrypted email system. That said, EPA's email system is compliant with all applicable Federal government information security provisions, including the Federal Information Security Management Act, and EPA's email systems meet the level of protection required for storing and transmitting CBI. Furthermore, your agreement will not constitute a waiver of substantive CBI protections, meaning that the information transmitted and claimed as confidential will only be disclosed consistent with TSCA, other applicable laws, and associated implementing regulations.

If you wish to grant EPA a limited waiver to transmit the materials via EPA's email system during the period in which a majority of EPA staff is teleworking, please have your authorized representative complete, sign, and return the attached to Greg Schweer ([Schweer.greg@epa.gov](mailto:Schweer.greg@epa.gov)) as well as to any EPA staff who were cc'd on the email sent to you. Also please follow the instructions below for the transmittal of information subject to this agreement. If you have any questions about this communication or the described process, please contact Greg Schweer at (202) 564-8469 or the EPA Program Manager assigned to the case, Drew Sullivan, at the number below.



Andrew (Drew) Sullivan | Program Manager  
New Chemicals Management Branch  
Chemical Control Division  
U.S. EPA Office of Pollution Prevention and Toxics  
Phone: 202-564-0605  
Fax: 202-564-9490  
DO NOT SEND CBI TO THIS EMAIL

**Agreement to authorize transmittal of TSCA Confidential Business Information (CBI) via Outlook email by designated Agency representatives during the period of EPA telework due to COVID-19**

Documents concerning: PMN-XX-XXX

**COMPANY** authorizes EPA to transmit documents related to the above referenced TSCA submission, including information claimed as CBI, to **COMPANY** (or its technical contact listed on the PMN form) through EPA's Outlook email system. This authorization applies only during those periods where EPA staff working on PMN-XX-XXX are teleworking due to COVID-19 concerns and may be withdrawn at any time. Nothing in this authorization diminishes or otherwise limits **COMPANY'S** protections under TSCA to assert information as CBI, or otherwise authorizes the release of any information claimed as CBI without exhausting all provisions of TSCA protecting the release of such information. I have the authority to sign this on behalf of **COMPANY**

Signature of authorized person: \_\_\_\_\_

Name of authorized person printed or typed: \_\_\_\_\_

Title: \_\_\_\_\_

Email address: \_\_\_\_\_

Telephone number: \_\_\_\_\_

**COMPANY** \_\_\_\_\_

Message

---

**From:** Berger, Tom C. [Berger@khlaw.com]  
**Sent:** 4/29/2020 3:12:07 PM  
**To:** Bauer, Jeff [Bauer.Jeff@epa.gov]  
**CC:** Price, Amanda [price@khlaw.com]; Schweer, Greg [Schweer.Greg@epa.gov]; Daniels, Rhys G. [daniels@khlaw.com]  
**Subject:** RE: **Ex. 4 CBI**

Hi Jeff --

I just thought I would check in on this and see if the Agency needs any additional information.

Thanks again and best regards,  
Tom

Thomas C. Berger  
Partner  
tel: 202.434.4285 | fax: 202.434.4646 | [berger@khlaw.com](mailto:berger@khlaw.com)  
1001 G Street, N.W., Suite 500 West | Washington, D.C. 20001

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**From:** Berger, Tom C.  
**Sent:** Thursday, April 23, 2020 7:13 PM  
**To:** 'Bauer, Jeff' <Bauer.Jeff@epa.gov>  
**Cc:** Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>  
**Subject:** RE: **Ex. 4 CBI**

Jeff - thanks much.

Your recent voicemail and follow-up email indicated that the EPA Chemist has evaluated the **Ex. 4 CBI** study" on **Ex. 4 CBI** **Ex. 4 CBI**, but that the reviewer did have a few questions and comments:

**Ex. 4 CBI**

# Ex. 4 CBI

To specifically answer the Chemist's questions:

# Ex. 4 CBI

# Ex. 4 CBI

\* \* \*

We trust that you find this information useful in resolved all outstanding issues. As always, if you have any questions please do not hesitate to contact us.

Best regards,  
Tom

Thomas C. Berger  
Partner  
tel: 202.434.4285 | fax: 202.434.4646 | [berger@khlaw.com](mailto:berger@khlaw.com)  
1001 G Street, N.W., Suite 500 West | Washington, D.C. 20001

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---

**From:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>  
**Sent:** Tuesday, April 21, 2020 5:17 PM  
**To:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>; Berger, Tom C. <[Berger@khlaw.com](mailto:Berger@khlaw.com)>

Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>

Subject: RE: Ex. 4 CBI

I am moving forward with the review based on the information I have on the two studies, I wanted to share with you her comments on the test. Ex. 4 CBI

Ex. 4 CBI RAD has the information and I am trying to get them to do the risk assessment based on Ex. 4 CBI

Jeff Bauer - Program Manager  
United States Environmental Protection Agency (USEPA)  
Office of Pollution Prevention and Toxics (OPPT)  
New Chemicals Program (7405M)  
<http://www.epa.gov/oppt/newchems/>

EPA East Building, room 4133M  
1201 Constitution Ave., NW  
Washington, DC 20004  
Phone: 202-564-9042, Fax: 202-564-9490

---

From: Daniels, Rhys G. <daniels@khlaw.com>

Sent: Tuesday, April 21, 2020 4:58 PM

To: Bauer, Jeff <Bauer.Jeff@epa.gov>; Berger, Tom C. <Berger@khlaw.com>

Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>

Subject: RE: Ex. 4 CBI

Jeff,

As always, we hope that all is well.

Per your recent voicemail and follow-up email concerning the Ex. 4 CBI case, we understand that the chemist has two questions concerning Ex. 4 CBI

**Ex. 4 CBI**

Thanks in advance for your response.

Rhys G. Daniels, Ph.D.  
Staff Scientist

tel: +1 202.434.4270 | fax: +1 202.434.4646 | [daniels@khlaw.com](mailto:daniels@khlaw.com)  
1001 G Street NW, Suite 500 West | Washington, DC 20001

---

**From:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>  
**Sent:** Thursday, April 16, 2020 1:02 PM  
**To:** Berger, Tom C. <[Berger@khlaw.com](mailto:Berger@khlaw.com)>  
**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>; Price, Amanda <[price@khlaw.com](mailto:price@khlaw.com)>; Schweer, Greg <[Schweer.Greg@epa.gov](mailto:Schweer.Greg@epa.gov)>  
**Subject:** RE: Ex. 4 CBI

Tom,

The chemist sent me a memo Ex. 4 CBI and they had two questions, I called and left you a message today Ex. 4 CBI I sent RAD a request last week to update the HH assessment Ex. 4 CBI Ex. 4 CBI as in my April 4, 2020 email to you. I have two emails into RAD on this case and will try an update you again in a week or so. I requested RAD set up a date with me to have a meeting to discuss how to proceed with this PMN.

Thanks  
Jeff

Jeff Bauer - Program Manager  
United States Environmental Protection Agency (USEPA)  
Office of Pollution Prevention and Toxics (OPPT)  
New Chemicals Program (7405M)  
<http://www.epa.gov/oppt/newchemicals/>

EPA East Building, room 4133M  
1201 Constitution Ave., NW  
Washington, DC 20004  
Phone: 202-564-9042, Fax: 202-564-9490

---

**From:** Berger, Tom C. <[Berger@khlaw.com](mailto:Berger@khlaw.com)>  
**Sent:** Thursday, April 16, 2020 12:28 PM  
**To:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>  
**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>; Price, Amanda <[price@khlaw.com](mailto:price@khlaw.com)>; Schweer, Greg <[Schweer.Greg@epa.gov](mailto:Schweer.Greg@epa.gov)>  
**Subject:** RE: Ex. 4 CBI

Hi Jeff –

I hope that all is well.

Just checking in re status update. A non-CBI-containing email from you would probably be the best (if needed at some later time we can use EPA's new CBI via email authorization form if the submitter agrees).

Thanks again – Tom

---

**From:** Berger, Tom C.  
**Sent:** Wednesday, April 8, 2020 11:06 AM  
**To:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>; Schweer, Greg <[Schweer.Greg@epa.gov](mailto:Schweer.Greg@epa.gov)>

Cc: Daniels, Rhys G. <daniels@khlaw.com>; Price, Amanda <price@khlaw.com>

Subject: RE: **Ex. 4 CBI**

Jeff – thanks much for the update. Hope you and all at EPA are staying safe.

Tom

---

**From:** Bauer, Jeff <Bauer.Jeff@epa.gov>

**Sent:** Wednesday, April 8, 2020 11:03 AM

**To:** Berger, Tom C. <Berger@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>

**Cc:** Daniels, Rhys G. <daniels@khlaw.com>; Price, Amanda <price@khlaw.com>

**Subject:** RE: **Ex. 4 CBI**

Tom,

# Ex. 4 CBI

I will follow up with you next wed with a status update.

Jeff Bauer - Program Manager  
United States Environmental Protection Agency (USEPA)  
Office of Pollution Prevention and Toxics (OPPT)  
New Chemicals Program (7405M)  
<http://www.epa.gov/oppt/newchems/>

EPA East Building, room 4133M  
1201 Constitution Ave., NW  
Washington, DC 20004  
Phone: 202-564-9042, Fax: 202-564-9490

---

**From:** Berger, Tom C. <Berger@khlaw.com>

**Sent:** Wednesday, April 08, 2020 10:48 AM

**To:** Schweer, Greg <Schweer.Greg@epa.gov>

**Cc:** Daniels, Rhys G. <daniels@khlaw.com>; Bauer, Jeff <Bauer.Jeff@epa.gov>; Price, Amanda <price@khlaw.com>

**Subject:** RE: **Ex. 4 CBI**

Hi Greg –

I was just going through my to-do list and thought I would circle back on these two cases. I hope everyone is hanging in there.

Thanks again – Tom

---

**From:** Berger, Tom C.

**Sent:** Monday, March 30, 2020 3:46 PM

**To:** Schweer, Greg <Schweer.Greg@epa.gov>

**Cc:** Daniels, Rhys G. <daniels@khlaw.com>; Bauer, Jeff <Bauer.Jeff@epa.gov>; Price, Amanda <price@khlaw.com>

**Subject:** RE: **Ex. 4 CBI**



Greg / all – completely understood – thank you so much.

Tom

---

**From:** Schweer, Greg <Schweer.Greg@epa.gov>  
**Sent:** Monday, March 30, 2020 3:42 PM  
**To:** Berger, Tom C. <Berger@khlaw.com>  
**Cc:** Daniels, Rhys G. <daniels@khlaw.com>; Bauer, Jeff <Bauer.Jeff@epa.gov>  
**Subject:** RE: **Ex. 4 CBI**

Hi Tom.

I am not ignoring you. I did check with Jeff Bauer early last week on this case. He filled me in on the requests he had made of RAD to review submitted test data and your request for a meeting. However, believe it or not, we have been having issues reliably being able to access our CBI-secure LAN. This hampers our ability to efficiently complete work. I will check on the status of your case as soon as I can.

---

**From:** Berger, Tom C. <Berger@khlaw.com>  
**Sent:** Monday, March 30, 2020 11:51 AM  
**To:** Schweer, Greg <Schweer.Greg@epa.gov>  
**Cc:** Daniels, Rhys G. <daniels@khlaw.com>  
**Subject:** RE: **Ex. 4 CBI**

Hi Greg –

Hope all is well.

Just thought I would check in with you on the **Ex. 4 CBI** LVEA (Lauren Davis) and **Ex. 4 CBI** **Ex. 4 CBI** with Jeff Bauer.

Thanks all always - Tom

---

**From:** Berger, Tom C.  
**Sent:** Tuesday, March 24, 2020 11:12 AM  
**To:** Schweer, Greg <Schweer.Greg@epa.gov>  
**Cc:** Daniels, Rhys G. <daniels@khlaw.com>  
**Subject:** RE: **Ex. 4 CBI**

Greg – thanks so much as always. I also have an LVE with Lauren Davis **Ex. 4 CBI** held up in the process. Lauren has been responsive but the case has stalled (again, however, I understand the challenges you are facing).

These are my two “priority” cases.

Tom

---

**From:** Schweer, Greg <Schweer.Greg@epa.gov>  
**Sent:** Tuesday, March 24, 2020 11:07 AM  
**To:** Berger, Tom C. <Berger@khlaw.com>  
**Cc:** Daniels, Rhys G. <daniels@khlaw.com>  
**Subject:** Re: **Ex. 4 CBI**

Tom,

Yes, things are a bit crazy. I will check into the case status today or tomorrow.

Sent from my iPhone

On Mar 24, 2020, at 10:48 AM, Berger, Tom C. <Berger@khlaw.com> wrote:

Hi Greg –

Obviously things are crazy and I don't want to push Jeff too hard but no response from Jeff on this case for a month.

Hang in there....

Tom

---

**From:** Berger, Tom C.  
**Sent:** Monday, March 23, 2020 6:22 PM  
**To:** Bauer, Jeff <Bauer.Jeff@epa.gov>  
**Cc:** Daniels, Rhys G. <daniels@khlaw.com>  
**Subject:** RE: **Ex. 4 CBI**

Hi Jeff –

Apologies – just want to make sure you are getting these emails. Understand if there are delays.

Tom

---

**From:** Berger, Tom C.  
**Sent:** Thursday, March 19, 2020 5:22 PM  
**To:** Bauer, Jeff <Bauer.Jeff@epa.gov>  
**Cc:** Daniels, Rhys G. <daniels@khlaw.com>  
**Subject:** RE: **Ex. 4 CBI**

Hi Jeff – checking in again – thanks - Tom

---

**From:** Berger, Tom C.  
**Sent:** Monday, March 16, 2020 1:40 PM  
**To:** Bauer, Jeff <Bauer.Jeff@epa.gov>  
**Cc:** Daniels, Rhys G. <daniels@khlaw.com>  
**Subject:** RE: **Ex. 4 CBI**

Hi Jeff –

I know things are crazy but checking in again – thanks - Tom

---

**From:** Berger, Tom C.  
**Sent:** Wednesday, March 11, 2020 3:43 PM

**To:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>  
**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>  
**Subject:** RE: **Ex. 4 CBI**

Hi Jeff –

Checking in again - thanks

---

**From:** Berger, Tom C.  
**Sent:** Friday, March 6, 2020 1:33 PM  
**To:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>  
**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>  
**Subject:** RE: **Ex. 4 CBI**

Hi Jeff –

The submitter is quite anxious – can we touch base next week?

Thanks much - Tom

---

**From:** Berger, Tom C.  
**Sent:** Tuesday, February 25, 2020 9:08 AM  
**To:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>  
**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>  
**Subject:** RE: **Ex. 4 CBI**

Hi Jeff –

Just checking in on this – thanks - Tom

---

**From:** Berger, Tom C.  
**Sent:** Thursday, February 20, 2020 12:18 PM  
**To:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>  
**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>  
**Subject:** RE: **Ex. 4 CBI**

Hi Jeff –

I hope that all is well.

Per our discussions, the submitter has modified the questions to focus on toxicity/risk issues and submitted them via CDX yesterday. Can we start looking at conference call dates the week of March 9?

Thanks and best regards,  
Tom

Thomas C. Berger  
Partner  
tel: 202.434.4285 | fax: 202.434.4646 | [berger@khlaw.com](mailto:berger@khlaw.com)  
1001 G Street, N.W., Suite 500 West | Washington, D.C. 20001

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---

**From:** Berger, Tom C.  
**Sent:** Wednesday, January 29, 2020 11:41 AM  
**To:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>  
**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>  
**Subject:** RE: **Ex. 4 CBI**

Hi Jeff –

Apologies we keep playing phone tag – can we discuss how to convert the below questions into questions that would be acceptable to RAD so we can schedule a call with you and RAD? Your voicemail suggested the below are more legal/regulatory than risk-based questions. We still need the below questions answered – perhaps we tee up the more scientific ones for RAD then have the call to address both types of questions. The submitter is under growing commercial pressure.

Thanks much again - Tom

---

**From:** Berger, Tom C.  
**Sent:** Monday, January 20, 2020 3:50 PM  
**To:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>  
**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>  
**Subject:** RE: **Ex. 4 CBI**

Hi Jeff –

Apologies that we could not connect last week. Let's try to touch base tomorrow (Tuesday) if possible to discuss how to move this forward.

Thanks again – Tom

Thomas C. Berger  
Partner  
tel: 202.434.4285 | fax: 202.434.4646 | [berger@khlaw.com](mailto:berger@khlaw.com)  
1001 G Street, N.W., Suite 500 West | Washington, D.C. 20001

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**From:** Berger, Tom C.  
**Sent:** Monday, January 13, 2020 2:50 PM  
**To:** Bauer, Jeff <Bauer.Jeff@epa.gov>  
**Cc:** Daniels, Rhys G. <daniels@khlaw.com>  
**Subject:** RE: **Ex. 4 CBI**  
**Importance:** High

Hi Jeff –

Following is the list of questions we are considering submitting through CDX. Please let me know if these look ok.

Thanks again and best regards,  
Tom

\* \* \*

*(1) Based on review of the submitted physical-chemical properties test data, does EPA now agree that use **Ex. 4 CBI** as described in the PMN poses no unreasonable risk of injury and so plans to revoke the consent order?*

*(2) If so, what is the process for revoking the current consent order? Does the submitter now need to request that EPA revoke the order, or will EPA itself initiate revocation? What is the expected timing for revocation? How would EPA communicate such revocation?*

*(3) How would revocation of the consent order impact the final SNUR for the subject substance?*

*(4) Would a SNUN be a more expedient approach?*

\* \* \*

---

**From:** Bauer, Jeff <Bauer.Jeff@epa.gov>  
**Sent:** Wednesday, January 8, 2020 8:56 AM  
**To:** Berger, Tom C. <Berger@khlaw.com>  
**Cc:** Daniels, Rhys G. <daniels@khlaw.com>  
**Subject:** RE: **Ex. 4 CBI**

Tom, I am expecting information from the engineer today or tomorrow on the **Ex. 4 CBI** test, I left you a message. There is a new procedure for us to set up meeting with RAD. I am to have the submitter send in a list of questions for RAD, they will assign someone up there as a Lead person who has two weeks and will set a date for when we can have a meeting. This may be our best route to other than just me bugging them to get things done. There were a series of emails on this case last week but now everyone is back from the holidays I am trying to get this case moving again.

Jeff Bauer - Program Manager  
United States Environmental Protection Agency (USEPA)  
Office of Pollution Prevention and Toxics (OPPT)  
New Chemicals Program (7405M)

<http://www.epa.gov/oppt/newchems/>

EPA East Building, room 4133M  
1201 Constitution Ave., NW  
Washington, DC 20004  
Phone: 202-564-9042, Fax: 202-564-9490

---

**From:** Berger, Tom C. <[Berger@khlaw.com](mailto:Berger@khlaw.com)>  
**Sent:** Tuesday, January 07, 2020 4:16 PM  
**To:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>  
**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>  
**Subject:** RE: **Ex. 4 CBI**

Hi Jeff –

I hope you had a great holiday! The client was wondering if we could have a conference call on this, this week or next. Please advise.

Thanks much – Tom

Thomas C. Berger  
Partner  
tel: 202.434.4285 | fax: 202.434.4646 | [berger@khlaw.com](mailto:berger@khlaw.com)  
1001 G Street, N.W., Suite 500 West | Washington, D.C. 20001

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**From:** Berger, Tom C.  
**Sent:** Tuesday, December 10, 2019 2:10 PM  
**To:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>  
**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>  
**Subject:** RE: **Ex. 4 CBI**

Hi Jeff –

Just checking back in – thanks - Tom

---

**From:** Berger, Tom C.  
**Sent:** Thursday, December 5, 2019 9:46 AM  
**To:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>  
**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>  
**Subject:** RE: **Ex. 4 CBI**

Hi Jeff –

When we spoke before Thanksgiving (I hope you had a great one!) you indicated that the reports were being reviewed and that I should reach out to you in early December.

Is there any update?

Thanks much and best regards – Tom

Thomas C. Berger

Partner

tel: 202.434.4285 | fax: 202.434.4646 | [berger@khlaw.com](mailto:berger@khlaw.com)

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**From:** Berger, Tom C.

**Sent:** Monday, November 18, 2019 1:17 PM

**To:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>

**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>

**Subject:** RE: **Ex. 4 CBI**

Hi Jeff –

The PMN submitter asked me to reach out to you to see if we can schedule a conference call (including EPA, K&H, and the submitter) on this case re status and pathforward.

Thanks - Tom

---

**From:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>

**Sent:** Friday, March 29, 2019 5:43 PM

**To:** Berger, Tom C. <[Berger@khlaw.com](mailto:Berger@khlaw.com)>; Schweer, Greg <[Schweer.Greg@epa.gov](mailto:Schweer.Greg@epa.gov)>

**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>

**Subject:** RE: **Ex. 4 CBI**

Tom,

I set the meeting up for Wednesday April 3, at 11 am. RAD has accepted the invitation for that time.

Jeff Bauer - Program Manager

United States Environmental Protection Agency (USEPA)

Office of Pollution Prevention and Toxics (OPPT)

New Chemicals Program (7405M)

<http://www.epa.gov/oppt/newchems/>

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Washington, DC 20004  
Phone: 202-564-9042, Fax: 202-564-9490

---

**From:** Bauer, Jeff  
**Sent:** Tuesday, March 26, 2019 11:37 AM  
**To:** 'Berger, Tom C.' <Berger@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>  
**Cc:** Daniels, Rhys G. <daniels@khlaw.com>  
**Subject:** RE: **Ex. 4 CBI**

Tom, I left you a voice message, I am seeing what time it best for RAD to be part of the call.

Jeff Bauer - Program Manager  
United States Environmental Protection Agency (USEPA)  
Office of Pollution Prevention and Toxics (OPPT)  
New Chemicals Program (7405M)  
<http://www.epa.gov/oppt/newchemicals/>

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1201 Constitution Ave., NW  
Washington, DC 20004  
Phone: 202-564-9042, Fax: 202-564-9490

---

**From:** Berger, Tom C. <Berger@khlaw.com>  
**Sent:** Tuesday, March 26, 2019 11:30 AM  
**To:** Bauer, Jeff <Bauer.Jeff@epa.gov>; Schweer, Greg <Schweer.Greg@epa.gov>  
**Cc:** Daniels, Rhys G. <daniels@khlaw.com>  
**Subject:** RE: **Ex. 4 CBI**

Hi folks –

Just thought I would check in with you on this.

Thanks again - Tom

---

**From:** Berger, Tom C.  
**Sent:** Friday, March 22, 2019 2:12 PM  
**To:** 'Bauer.jeff@Epa.gov' <Bauer.jeff@Epa.gov>; 'Schweer, Greg' <Schweer.Greg@epa.gov>  
**Cc:** Daniels, Rhys G. <daniels@khlaw.com>  
**Subject:** **Ex. 4 CBI**

Hi folks –

I hope you are doing well. Jeff – this is the PMN case that my colleague, Dr. Rhys Daniels, spoke with you about earlier this week.

The issue is development of data needed to amend the existing section 5(e) order for this substance to add an additional use, and EPA approval of protocols for same. Would the Agency be available for a short conference call on this on one of the following days?:

- March 27 (except 12-2 ET)



- April 2
- April 3
- April 4

This is becoming more urgent from a commercial standpoint.

Thanks much - Tom

Thomas C. Berger

Partner

tel: 202.434.4285 | fax: 202.434.4646 | [berger@khlaw.com](mailto:berger@khlaw.com)

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Message

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**From:** Berger, Tom C. [Berger@khlaw.com]  
**Sent:** 4/28/2020 2:52:01 PM  
**To:** Davis, Lauren O. [Davis.LaurenO@epa.gov]  
**CC:** Schweer, Greg [Schweer.Greg@epa.gov]; Harney, Matthew B. [harney@khlaw.com]; Price, Amanda [price@khlaw.com]  
**Subject:** RE: LVEA

**Importance:** High

Lauren – thanks again.

I recognize that the Agency's analysis is not complete, but is the Agency contemplating upfront toxicological or physical property testing, production volume triggered testing, specified respiratory protection, etc.? I'm a bit surprised that a section 5(e) order is being contemplated, as most if not all concerns have been addressed, and this substance provides significant environmental benefits.

Tom

---

**From:** Davis, Lauren O. <Davis.LaurenO@epa.gov>  
**Sent:** Tuesday, April 28, 2020 9:30 AM  
**To:** Berger, Tom C. <Berger@khlaw.com>  
**Cc:** Schweer, Greg <Schweer.Greg@epa.gov>; Harney, Matthew B. <harney@khlaw.com>; Price, Amanda <price@khlaw.com>  
**Subject:** Re: LVEA

Hi Tom,

This case may be regulated by a Consent Order. I cannot comment on timing for finalization at the moment because a science policy decision must be made by the Risk Assessment Division for all lung toxicity cases.

Best,  
Lauren  
202-564-0528

---

**From:** Berger, Tom C. <Berger@khlaw.com>  
**Sent:** Monday, April 27, 2020 5:31 PM  
**To:** Davis, Lauren O. <Davis.LaurenO@epa.gov>  
**Cc:** Schweer, Greg <Schweer.Greg@epa.gov>; Harney, Matthew B. <harney@khlaw.com>; Price, Amanda <price@khlaw.com>  
**Subject:** RE: LVEA

Ok – thanks – can the Agency say anything about how the substance might be regulated? Estimated timing for finalization of the RA?

Thanks again - Tom

---

**From:** Davis, Lauren O. <Davis.LaurenO@epa.gov>  
**Sent:** Monday, April 27, 2020 5:17 PM  
**To:** Berger, Tom C. <Berger@khlaw.com>

**Cc:** Schweer, Greg <[Schweer.Greg@epa.gov](mailto:Schweer.Greg@epa.gov)>; Harney, Matthew B. <[harney@khlaw.com](mailto:harney@khlaw.com)>; Price, Amanda <[price@khlaw.com](mailto:price@khlaw.com)>

**Subject:** Re: LVEA

Hi Tom,

## Ex. 5 Deliberative Process (DP)

Best,  
Lauren  
202-564-0528

---

**From:** Berger, Tom C. <[Berger@khlaw.com](mailto:Berger@khlaw.com)>

**Sent:** Monday, April 27, 2020 3:33 PM

**To:** Davis, Lauren O. <[Davis.LaurenO@epa.gov](mailto:Davis.LaurenO@epa.gov)>

**Cc:** Schweer, Greg <[Schweer.Greg@epa.gov](mailto:Schweer.Greg@epa.gov)>; Harney, Matthew B. <[harney@khlaw.com](mailto:harney@khlaw.com)>; Price, Amanda <[price@khlaw.com](mailto:price@khlaw.com)>

**Subject:** RE: LVEA

Lauren – thanks much.

The submitter has a Company meeting tomorrow at 11:00 am PST and they requested that I ask the Agency for an update. Can you provide one?

Thanks again - Tom

---

**From:** Davis, Lauren O. <[Davis.LaurenO@epa.gov](mailto:Davis.LaurenO@epa.gov)>

**Sent:** Thursday, April 16, 2020 9:47 AM

**To:** Berger, Tom C. <[Berger@khlaw.com](mailto:Berger@khlaw.com)>

**Cc:** Schweer, Greg <[Schweer.Greg@epa.gov](mailto:Schweer.Greg@epa.gov)>; Harney, Matthew B. <[harney@khlaw.com](mailto:harney@khlaw.com)>; Price, Amanda <[price@khlaw.com](mailto:price@khlaw.com)>

**Subject:** Re: LVEA

Hi Tom,

## Ex. 5 Deliberative Process (DP)

I will be able to give you an update after this discussion takes place.

Best,  
Lauren

---

**From:** Berger, Tom C. <[Berger@khlaw.com](mailto:Berger@khlaw.com)>  
**Sent:** Thursday, April 16, 2020 9:21 AM  
**To:** Davis, Lauren O. <[Davis.LaurenO@epa.gov](mailto:Davis.LaurenO@epa.gov)>  
**Cc:** Schweer, Greg <[Schweer.Greg@epa.gov](mailto:Schweer.Greg@epa.gov)>; Harney, Matthew B. <[harney@khlaw.com](mailto:harney@khlaw.com)>; Price, Amanda <[price@khlaw.com](mailto:price@khlaw.com)>  
**Subject:** RE: LVEA

Thanks – I may not be able to access a phone before my 11:00 call so if you could in a short email describe where this case stands that would be great. So long as you don't include the PMN number or any other quantitative information it will be non-CBI so we can use email (at some later point we may want or need to use the new email CBI authorization form that I received for another client).

Thanks again - Tom

---

**From:** Davis, Lauren O. <[Davis.LaurenO@epa.gov](mailto:Davis.LaurenO@epa.gov)>  
**Sent:** Thursday, April 16, 2020 9:14 AM  
**To:** Berger, Tom C. <[Berger@khlaw.com](mailto:Berger@khlaw.com)>  
**Cc:** Schweer, Greg <[Schweer.Greg@epa.gov](mailto:Schweer.Greg@epa.gov)>; Harney, Matthew B. <[harney@khlaw.com](mailto:harney@khlaw.com)>; Price, Amanda <[price@khlaw.com](mailto:price@khlaw.com)>  
**Subject:** Re: LVEA

Good morning Tom,

I just left you a voice message about this PMN. Please feel free to give me a call back at your earliest convenience.

I hope that you are doing well too.

Best regards,  
Lauren  
202-564-0528

---

**From:** Berger, Tom C. <[Berger@khlaw.com](mailto:Berger@khlaw.com)>  
**Sent:** Tuesday, April 14, 2020 2:58 PM  
**To:** Davis, Lauren O. <[Davis.LaurenO@epa.gov](mailto:Davis.LaurenO@epa.gov)>  
**Cc:** Schweer, Greg <[Schweer.Greg@epa.gov](mailto:Schweer.Greg@epa.gov)>; Harney, Matthew B. <[harney@khlaw.com](mailto:harney@khlaw.com)>; Price, Amanda <[price@khlaw.com](mailto:price@khlaw.com)>  
**Subject:** RE: LVEA

Just as a follow-up, we are having a conference call with the submitter Thursday (4/16) at 11:00 ET, so an update by that time would be greatly appreciated.

Thanks again - Tom

---

**From:** Berger, Tom C.  
**Sent:** Tuesday, April 14, 2020 9:10 AM  
**To:** [Davis.laureno@Epa.gov](mailto:Davis.laureno@Epa.gov)

**Cc:** Schweer, Greg <[Schweer.Greg@epa.gov](mailto:Schweer.Greg@epa.gov)>; Harney, Matthew B. <[harney@khlaw.com](mailto:harney@khlaw.com)>; Price, Amanda <[price@khlaw.com](mailto:price@khlaw.com)>

**Subject:** LVEA

Hi Lauren –

I hope that all is well!

Recall that we had discussed an LVEA where a Green Chemistry award winner is held up in the process and risks significant commercial disruption (if not bankruptcy). They have requested an update. Can you provide one?

Thanks again – Tom

Thomas C. Berger

Partner

tel: 202.434.4285 | fax: 202.434.4646 | [berger@khlaw.com](mailto:berger@khlaw.com)

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Message

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**From:** Berger, Tom C. [Berger@khlaw.com]  
**Sent:** 4/23/2020 11:13:27 PM  
**To:** Bauer, Jeff [Bauer.Jeff@epa.gov]  
**CC:** Price, Amanda [price@khlaw.com]; Schweer, Greg [Schweer.Greg@epa.gov]; Daniels, Rhys G. [daniels@khlaw.com]  
**Subject:** RE: **Ex. 4 CBI**

Jeff - thanks much.

Your recent voicemail and follow-up email indicated that the EPA Chemist has evaluated the **Ex. 4 CBI** study" on **Ex. 4 CBI** **Ex. 4 CBI** but that the reviewer did have a few questions and comments:

**Ex. 4 CBI**

To specifically answer the Chemist's questions:

# Ex. 4 CBI

\* \* \*

We trust that you find this information useful in resolved all outstanding issues. As always, if you have any questions please do not hesitate to contact us.

Best regards,  
Tom

Thomas C. Berger  
Partner  
tel: 202.434.4285 | fax: 202.434.4646 | [berger@khlaw.com](mailto:berger@khlaw.com)  
1001 G Street, N.W., Suite 500 West | Washington, D.C. 20001

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**From:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>  
**Sent:** Tuesday, April 21, 2020 5:17 PM  
**To:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>; Berger, Tom C. <[Berger@khlaw.com](mailto:Berger@khlaw.com)>  
**Cc:** Price, Amanda <[price@khlaw.com](mailto:price@khlaw.com)>; Schweer, Greg <[Schweer.Greg@epa.gov](mailto:Schweer.Greg@epa.gov)>  
**Subject:** RE: Ex. 4 CBI

I am moving forward with the review based on the information I have on the two studies, I wanted to share with you her comments on the test. Ex. 4 CBI

Ex. 4 CBI RAD has the information and I am trying to get them to do the risk assessment based on Ex. 4 CBI

Jeff Bauer - Program Manager  
United States Environmental Protection Agency (USEPA)  
Office of Pollution Prevention and Toxics (OPPT)  
New Chemicals Program (7405M)  
<http://www.epa.gov/oppt/newchems/>

EPA East Building, room 4133M  
1201 Constitution Ave., NW  
Washington, DC 20004  
Phone: 202-564-9042, Fax: 202-564-9490

---

**From:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>  
**Sent:** Tuesday, April 21, 2020 4:58 PM  
**To:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>; Berger, Tom C. <[Berger@khlaw.com](mailto:Berger@khlaw.com)>  
**Cc:** Price, Amanda <[price@khlaw.com](mailto:price@khlaw.com)>; Schweer, Greg <[Schweer.Greg@epa.gov](mailto:Schweer.Greg@epa.gov)>  
**Subject:** RE: Ex. 4 CBI

Jeff,

As always, we hope that all is well.



Per your recent voicemail and follow-up email concerning the **Ex. 4 CBI** case, we understand that the chemist has two questions concerning **Ex. 4 CBI**

# Ex. 4 CBI

Thanks in advance for your response.

Rhys G. Daniels, Ph.D.

Staff Scientist

tel: +1 202.434.4270 | fax: +1 202.434.4646 | [daniels@khlaw.com](mailto:daniels@khlaw.com)

1001 G Street NW, Suite 500 West | Washington, DC 20001

---

**From:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>

**Sent:** Thursday, April 16, 2020 1:02 PM

**To:** Berger, Tom C. <[Berger@khlaw.com](mailto:Berger@khlaw.com)>

**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>; Price, Amanda <[price@khlaw.com](mailto:price@khlaw.com)>; Schweer, Greg <[Schweer.Greg@epa.gov](mailto:Schweer.Greg@epa.gov)>

**Subject:** RE: **Ex. 4 CBI**

Tom,

The chemist sent me a memo **Ex. 4 CBI** and they had two questions, I called and left you a message today **Ex. 4 CBI** I sent RAD a request last week to update the HH assessment **Ex. 4 CBI** **Ex. 4 CBI** as in my April 4, 2020 email to you. I have two emails into RAD on this case and will try an update you again in a week or so. I requested RAD set up a date with me to have a meeting to discuss how to proceed with this PMN.

Thanks

Jeff

Jeff Bauer - Program Manager

United States Environmental Protection Agency (USEPA)

Office of Pollution Prevention and Toxics (OPPT)

New Chemicals Program (7405M)

<http://www.epa.gov/oppt/newchemicals/>

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---

**From:** Berger, Tom C. <Berger@khlaw.com>  
**Sent:** Thursday, April 16, 2020 12:28 PM  
**To:** Bauer, Jeff <Bauer.Jeff@epa.gov>  
**Cc:** Daniels, Rhys G. <daniels@khlaw.com>; Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>  
**Subject:** RE: **Ex. 4 CBI**

Hi Jeff –

I hope that all is well.

Just checking in re status update. A non-CBI-containing email from you would probably be the best (if needed at some later time we can use EPA's new CBI via email authorization form if the submitter agrees).

Thanks again – Tom

---

**From:** Berger, Tom C.  
**Sent:** Wednesday, April 8, 2020 11:06 AM  
**To:** Bauer, Jeff <Bauer.Jeff@epa.gov>; Schweer, Greg <Schweer.Greg@epa.gov>  
**Cc:** Daniels, Rhys G. <daniels@khlaw.com>; Price, Amanda <price@khlaw.com>  
**Subject:** RE: **Ex. 4 CBI**

Jeff – thanks much for the update. Hope you and all at EPA are staying safe.

Tom

---

**From:** Bauer, Jeff <Bauer.Jeff@epa.gov>  
**Sent:** Wednesday, April 8, 2020 11:03 AM  
**To:** Berger, Tom C. <Berger@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>  
**Cc:** Daniels, Rhys G. <daniels@khlaw.com>; Price, Amanda <price@khlaw.com>  
**Subject:** RE: **Ex. 4 CBI**

Tom,

# Ex. 4 CBI

I will follow up with you next wed with a status update.

Jeff Bauer - Program Manager  
United States Environmental Protection Agency (USEPA)  
Office of Pollution Prevention and Toxics (OPPT)  
New Chemicals Program (7405M)  
<http://www.epa.gov/oppt/newchemicals/>

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---

**From:** Berger, Tom C. <Berger@khlaw.com>  
**Sent:** Wednesday, April 08, 2020 10:48 AM  
**To:** Schweer, Greg <Schweer.Greg@epa.gov>  
**Cc:** Daniels, Rhys G. <daniels@khlaw.com>; Bauer, Jeff <Bauer.Jeff@epa.gov>; Price, Amanda <price@khlaw.com>  
**Subject:** RE: **Ex. 4 CBI**

Hi Greg –

I was just going through my to-do list and thought I would circle back on these two cases. I hope everyone is hanging in there.

Thanks again – Tom

---

**From:** Berger, Tom C.  
**Sent:** Monday, March 30, 2020 3:46 PM  
**To:** Schweer, Greg <Schweer.Greg@epa.gov>  
**Cc:** Daniels, Rhys G. <daniels@khlaw.com>; Bauer, Jeff <Bauer.Jeff@epa.gov>; Price, Amanda <price@khlaw.com>  
**Subject:** RE: **Ex. 4 CBI**

Greg / all – completely understood – thank you so much.

Tom

---

**From:** Schweer, Greg <Schweer.Greg@epa.gov>  
**Sent:** Monday, March 30, 2020 3:42 PM  
**To:** Berger, Tom C. <Berger@khlaw.com>  
**Cc:** Daniels, Rhys G. <daniels@khlaw.com>; Bauer, Jeff <Bauer.Jeff@epa.gov>  
**Subject:** RE: **Ex. 4 CBI**

Hi Tom.

I am not ignoring you. I did check with Jeff Bauer early last week on this case. He filled me in on the requests he had made of RAD to review submitted test data and your request for a meeting. However, believe it or not, we have been having issues reliably being able to access our CBI-secure LAN. This hampers our ability to efficiently complete work. I will check on the status of your case as soon as I can.

---

**From:** Berger, Tom C. <Berger@khlaw.com>  
**Sent:** Monday, March 30, 2020 11:51 AM  
**To:** Schweer, Greg <Schweer.Greg@epa.gov>  
**Cc:** Daniels, Rhys G. <daniels@khlaw.com>  
**Subject:** RE: **Ex. 4 CBI**

Hi Greg –

Hope all is well.

Just thought I would check in with you on the **Ex. 4 CBI** with Jeff Bauer.

**Ex. 4 CBI**

LVEA (Lauren Davis) and

**Ex. 4 CBI**

Thanks all always - Tom

---

**From:** Berger, Tom C.

**Sent:** Tuesday, March 24, 2020 11:12 AM

**To:** Schweer, Greg <Schweer.Greg@epa.gov>

**Cc:** Daniels, Rhys G. <daniels@khlaw.com>

**Subject:** RE: **Ex. 4 CBI**

Greg – thanks so much as always. I also have an LVE with Lauren Davis: **Ex. 4 CBI** held up in the process. Lauren has been responsive but the case has stalled (again, however, I understand the challenges you are facing).

These are my two “priority” cases.

Tom

---

**From:** Schweer, Greg <Schweer.Greg@epa.gov>

**Sent:** Tuesday, March 24, 2020 11:07 AM

**To:** Berger, Tom C. <Berger@khlaw.com>

**Cc:** Daniels, Rhys G. <daniels@khlaw.com>

**Subject:** Re: **Ex. 4 CBI**

Tom,

Yes, things are a bit crazy. I will check into the case status today or tomorrow.

Sent from my iPhone

On Mar 24, 2020, at 10:48 AM, Berger, Tom C. <Berger@khlaw.com> wrote:

Hi Greg –

Obviously things are crazy and I don't want to push Jeff too hard but no response from Jeff on this case for a month.

Hang in there....

Tom

---

**From:** Berger, Tom C.

**Sent:** Monday, March 23, 2020 6:22 PM

**To:** Bauer, Jeff <Bauer.Jeff@epa.gov>

**Cc:** Daniels, Rhys G. <daniels@khlaw.com>

**Subject:** RE: **Ex. 4 CBI**

Hi Jeff –

Apologies – just want to make sure you are getting these emails. Understand if there are delays.

Tom

---

**From:** Berger, Tom C.  
**Sent:** Thursday, March 19, 2020 5:22 PM  
**To:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>  
**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>  
**Subject:** RE: **Ex. 4 CBI**

Hi Jeff – checking in again – thanks - Tom

---

**From:** Berger, Tom C.  
**Sent:** Monday, March 16, 2020 1:40 PM  
**To:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>  
**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>  
**Subject:** RE: **Ex. 4 CBI**

Hi Jeff –

I know things are crazy but checking in again – thanks - Tom

---

**From:** Berger, Tom C.  
**Sent:** Wednesday, March 11, 2020 3:43 PM  
**To:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>  
**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>  
**Subject:** RE: **Ex. 4 CBI**

Hi Jeff –

Checking in again - thanks

---

**From:** Berger, Tom C.  
**Sent:** Friday, March 6, 2020 1:33 PM  
**To:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>  
**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>  
**Subject:** RE: **Ex. 4 CBI**

Hi Jeff –

The submitter is quite anxious – can we touch base next week?

Thanks much - Tom

---

**From:** Berger, Tom C.  
**Sent:** Tuesday, February 25, 2020 9:08 AM  
**To:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>  
**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>  
**Subject:** RE: **Ex. 4 CBI**

Hi Jeff –

Just checking in on this – thanks - Tom

---

**From:** Berger, Tom C.  
**Sent:** Thursday, February 20, 2020 12:18 PM  
**To:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>  
**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>  
**Subject:** RE: Ex. 4 CBI

Hi Jeff –

I hope that all is well.

Per our discussions, the submitter has modified the questions to focus on toxicity/risk issues and submitted them via CDX yesterday. Can we start looking at conference call dates the week of March 9?

Thanks and best regards,  
Tom

Thomas C. Berger  
Partner  
tel: 202.434.4285 | fax: 202.434.4646 | [berger@khlaw.com](mailto:berger@khlaw.com)  
1001 G Street, N.W., Suite 500 West | Washington, D.C. 20001

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---

**From:** Berger, Tom C.  
**Sent:** Wednesday, January 29, 2020 11:41 AM  
**To:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>  
**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>  
**Subject:** RE: Ex. 4 CBI

Hi Jeff –

Apologies we keep playing phone tag – can we discuss how to convert the below questions into questions that would be acceptable to RAD so we can schedule a call with you and RAD? Your voicemail suggested the below are more legal/regulatory than risk-based questions. We still need the below questions answered – perhaps we tee up the more scientific ones for RAD then have the call to address both types of questions. The submitter is under growing commercial pressure.

Thanks much again - Tom

---

**From:** Berger, Tom C.  
**Sent:** Monday, January 20, 2020 3:50 PM  
**To:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>

**Cc:** Daniels, Rhys G. <daniels@khlaw.com>

**Subject:** RE: **Ex. 4 CBI**

Hi Jeff –

Apologies that we could not connect last week. Let's try to touch base tomorrow (Tuesday) if possible to discuss how to move this forward.

Thanks again – Tom

Thomas C. Berger

Partner

tel: 202.434.4285 | fax: 202.434.4646 | [berger@khlaw.com](mailto:berger@khlaw.com)  
1001 G Street, N.W., Suite 500 West | Washington, D.C. 20001

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---

**From:** Berger, Tom C.

**Sent:** Monday, January 13, 2020 2:50 PM

**To:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>

**Cc:** Daniels, Rhys G. <daniels@khlaw.com>

**Subject:** RE: **Ex. 4 CBI**

**Importance:** High

Hi Jeff –

Following is the list of questions we are considering submitting through CDX. Please let me know if these look ok.

Thanks again and best regards,  
Tom

\* \* \*

*(1) Based on review of the submitted physical-chemical properties test data, does EPA now agree that use of **Ex. 4 CBI** as described in the PMN poses no unreasonable risk of injury and so plans to revoke the consent order?*

*(2) If so, what is the process for revoking the current consent order? Does the submitter now need to request that EPA revoke the order, or will EPA itself initiate revocation? What is the expected timing for revocation? How would EPA communicate such revocation?*

*(3) How would revocation of the consent order impact the final SNUR for the subject substance?*

(4) Would a SNUN be a more expedient approach?

\* \* \*

---

**From:** Bauer, Jeff <Bauer.Jeff@epa.gov>  
**Sent:** Wednesday, January 8, 2020 8:56 AM  
**To:** Berger, Tom C. <Berger@khlaw.com>  
**Cc:** Daniels, Rhys G. <daniels@khlaw.com>  
**Subject:** RE: Ex. 4 CBI

Tom, I am expecting information from the engineer today or tomorrow on the Ex. 4 CBI test, I left you a message. There is a new procedure for us to set up meeting with RAD. I am to have the submitter send in a list of questions for RAD, they will assign someone up there as a Lead person who has two weeks and will set a date for when we can have a meeting. This may be our best route to other than just me bugging them to get things done. There were a series of emails on this case last week but now everyone is back from the holidays I am trying to get this case moving again.

Jeff Bauer - Program Manager  
United States Environmental Protection Agency (USEPA)  
Office of Pollution Prevention and Toxics (OPPT)  
New Chemicals Program (7405M)  
<http://www.epa.gov/oppt/newchems/>

EPA East Building, room 4133M  
1201 Constitution Ave., NW  
Washington, DC 20004  
Phone: 202-564-9042, Fax: 202-564-9490

---

**From:** Berger, Tom C. <Berger@khlaw.com>  
**Sent:** Tuesday, January 07, 2020 4:16 PM  
**To:** Bauer, Jeff <Bauer.Jeff@epa.gov>  
**Cc:** Daniels, Rhys G. <daniels@khlaw.com>  
**Subject:** RE: Ex. 4 CBI

Hi Jeff –

I hope you had a great holiday! The client was wondering if we could have a conference call on this, this week or next. Please advise.

Thanks much – Tom

Thomas C. Berger  
Partner  
tel: 202.434.4285 | fax: 202.434.4646 | [berger@khlaw.com](mailto:berger@khlaw.com)  
1001 G Street, N.W., Suite 500 West | Washington, D.C. 20001

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**From:** Berger, Tom C.  
**Sent:** Tuesday, December 10, 2019 2:10 PM  
**To:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>  
**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>  
**Subject:** RE: **Ex. 4 CBI**

Hi Jeff –

Just checking back in – thanks - Tom

---

**From:** Berger, Tom C.  
**Sent:** Thursday, December 5, 2019 9:46 AM  
**To:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>  
**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>  
**Subject:** RE: **Ex. 4 CBI**

Hi Jeff –

When we spoke before Thanksgiving (I hope you had a great one!) you indicated that the reports were being reviewed and that I should reach out to you in early December.

Is there any update?

Thanks much and best regards – Tom

Thomas C. Berger  
Partner  
tel: 202.434.4285 | fax: 202.434.4646 | [berger@khlaw.com](mailto:berger@khlaw.com)  
1001 G Street, N.W., Suite 500 West | Washington, D.C. 20001

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**From:** Berger, Tom C.  
**Sent:** Monday, November 18, 2019 1:17 PM  
**To:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>  
**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>  
**Subject:** RE: **Ex. 4 CBI**

Hi Jeff –

The PMN submitter asked me to reach out to you to see if we can schedule a conference call (including EPA, K&H, and the submitter) on this case re status and pathforward.

Thanks - Tom

---

**From:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>  
**Sent:** Friday, March 29, 2019 5:43 PM  
**To:** Berger, Tom C. <[Berger@khlaw.com](mailto:Berger@khlaw.com)>; Schweer, Greg <[Schweer.Greg@epa.gov](mailto:Schweer.Greg@epa.gov)>  
**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>  
**Subject:** RE: **Ex. 4 CBI**

Tom,  
I set the meeting up for Wednesday April 3, at 11 am. RAD has accepted the invitation for that time.

Jeff Bauer - Program Manager  
United States Environmental Protection Agency (USEPA)  
Office of Pollution Prevention and Toxics (OPPT)  
New Chemicals Program (7405M)  
<http://www.epa.gov/oppt/newchems/>

EPA East Building, room 4133M  
1201 Constitution Ave., NW  
Washington, DC 20004  
Phone: 202-564-9042, Fax: 202-564-9490

---

**From:** Bauer, Jeff  
**Sent:** Tuesday, March 26, 2019 11:37 AM  
**To:** 'Berger, Tom C.' <[Berger@khlaw.com](mailto:Berger@khlaw.com)>; Schweer, Greg <[Schweer.Greg@epa.gov](mailto:Schweer.Greg@epa.gov)>  
**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>  
**Subject:** RE: **Ex. 4 CBI**

Tom, I left you a voice message, I am seeing what time it best for RAD to be part of the call.

Jeff Bauer - Program Manager  
United States Environmental Protection Agency (USEPA)  
Office of Pollution Prevention and Toxics (OPPT)  
New Chemicals Program (7405M)  
<http://www.epa.gov/oppt/newchems/>

EPA East Building, room 4133M  
1201 Constitution Ave., NW  
Washington, DC 20004  
Phone: 202-564-9042, Fax: 202-564-9490

---

**From:** Berger, Tom C. <[Berger@khlaw.com](mailto:Berger@khlaw.com)>  
**Sent:** Tuesday, March 26, 2019 11:30 AM  
**To:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>; Schweer, Greg <[Schweer.Greg@epa.gov](mailto:Schweer.Greg@epa.gov)>  
**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>  
**Subject:** RE: **Ex. 4 CBI**

Hi folks –

Just thought I would check in with you on this.

Thanks again - Tom

---

**From:** Berger, Tom C.

**Sent:** Friday, March 22, 2019 2:12 PM

**To:** 'Bauer.jeff@Epa.gov' <[Bauer.jeff@Epa.gov](mailto:Bauer.jeff@Epa.gov)>; 'Schweer, Greg' <[Schweer.Greg@epa.gov](mailto:Schweer.Greg@epa.gov)>

**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>

**Subject:** **Ex. 4 CBI**

Hi folks –

I hope you are doing well. Jeff – this is the PMN case that my colleague, Dr. Rhys Daniels, spoke with you about earlier this week.

The issue is development of data needed to amend the existing section 5(e) order for this substance to add an additional use, and EPA approval of protocols for same. Would the Agency be available for a short conference call on this on one of the following days?:

- March 27 (except 12-2 ET)
- April 2
- April 3
- April 4

This is becoming more urgent from a commercial standpoint.

Thanks much - Tom

Thomas C. Berger

Partner

tel: 202.434.4285 | fax: 202.434.4646 | [berger@khlaw.com](mailto:berger@khlaw.com)

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including review, dissemination, distribution, copying, or disclosure, is strictly prohibited. If you are not a designated addressee (or an authorized agent), we request that you immediately notify us of this error by reply e-mail and then delete it from your system.

Message

**From:** Bauer, Jeff [Bauer.Jeff@epa.gov]  
**Sent:** 4/21/2020 9:16:55 PM  
**To:** Daniels, Rhys G. [daniels@khlaw.com]; Berger, Tom C. [Berger@khlaw.com]  
**CC:** Price, Amanda [price@khlaw.com]; Schweer, Greg [Schweer.Greg@epa.gov]  
**Subject:** RE: **Ex. 4 CBI**

I am moving forward with the review based on the information I have on the two studies, I wanted to share with you her comments on the test. **Ex. 4 CBI**

**Ex. 4 CBI** RAD has the information and I am trying to get them to do the risk assessment based on **Ex. 4 CBI**

Jeff Bauer - Program Manager  
United States Environmental Protection Agency (USEPA)  
Office of Pollution Prevention and Toxics (OPPT)  
New Chemicals Program (7405M)  
<http://www.epa.gov/oppt/newchems/>

EPA East Building, room 4133M  
1201 Constitution Ave., NW  
Washington, DC 20004  
Phone: 202-564-9042, Fax: 202-564-9490

---

**From:** Daniels, Rhys G. <daniels@khlaw.com>  
**Sent:** Tuesday, April 21, 2020 4:58 PM  
**To:** Bauer, Jeff <Bauer.Jeff@epa.gov>; Berger, Tom C. <Berger@khlaw.com>  
**Cc:** Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>  
**Subject:** RE: **Ex. 4 CBI**

Jeff,

As always, we hope that all is well.

Per your recent voicemail and follow-up email concerning the **Ex. 4 CBI** case, we understand that the chemist has two questions concerning **Ex. 4 CBI**

**Ex. 4 CBI**

Thanks in advance for your response.

Rhys G. Daniels, Ph.D.  
Staff Scientist  
[tel: +1 202.434.4270](tel:+1202.434.4270) | [fax: +1 202.434.4646](tel:+1202.434.4646) | [daniels@khlaw.com](mailto:daniels@khlaw.com)  
1001 G Street NW, Suite 500 West | Washington, DC 20001

---

**From:** Bauer, Jeff <Bauer.Jeff@epa.gov>  
**Sent:** Thursday, April 16, 2020 1:02 PM  
**To:** Berger, Tom C. <Berger@khlaw.com>  
**Cc:** Daniels, Rhys G. <daniels@khlaw.com>; Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>  
**Subject:** RE: Ex. 4 CBI

Tom,

The chemist sent me a memo Ex. 4 CBI and they had two questions, I called and left you a message today Ex. 4 CBI I sent RAD a request last week to update the HH assessment Ex. 4 CBI Ex. 4 CBI as in my April 4, 2020 email to you. I have two emails into RAD on this case and will try an update you again in a week or so. I requested RAD set up a date with me to have a meeting to discuss how to proceed with this PMN.

Thanks  
Jeff

Jeff Bauer - Program Manager  
United States Environmental Protection Agency (USEPA)  
Office of Pollution Prevention and Toxics (OPPT)  
New Chemicals Program (7405M)  
<http://www.epa.gov/oppt/newchems/>

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Phone: 202-564-9042, Fax: 202-564-9490

---

**From:** Berger, Tom C. <Berger@khlaw.com>  
**Sent:** Thursday, April 16, 2020 12:28 PM  
**To:** Bauer, Jeff <Bauer.Jeff@epa.gov>  
**Cc:** Daniels, Rhys G. <daniels@khlaw.com>; Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>  
**Subject:** RE: Ex. 4 CBI

Hi Jeff –

I hope that all is well.

Just checking in re status update. A non-CBI-containing email from you would probably be the best (if needed at some later time we can use EPA's new CBI via email authorization form if the submitter agrees).

Thanks again – Tom

---

**From:** Berger, Tom C.  
**Sent:** Wednesday, April 8, 2020 11:06 AM  
**To:** Bauer, Jeff <Bauer.Jeff@epa.gov>; Schweer, Greg <Schweer.Greg@epa.gov>  
**Cc:** Daniels, Rhys G. <daniels@khlaw.com>; Price, Amanda <price@khlaw.com>  
**Subject:** RE: **Ex. 4 CBI**

Jeff – thanks much for the update. Hope you and all at EPA are staying safe.

Tom

---

**From:** Bauer, Jeff <Bauer.Jeff@epa.gov>  
**Sent:** Wednesday, April 8, 2020 11:03 AM  
**To:** Berger, Tom C. <Berger@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>  
**Cc:** Daniels, Rhys G. <daniels@khlaw.com>; Price, Amanda <price@khlaw.com>  
**Subject:** RE: **Ex. 4 CBI**

Tom,

# Ex. 4 CBI

I will follow up with you next wed with a status update.

Jeff Bauer - Program Manager  
United States Environmental Protection Agency (USEPA)  
Office of Pollution Prevention and Toxics (OPPT)  
New Chemicals Program (7405M)  
<http://www.epa.gov/oppt/newchems/>

EPA East Building, room 4133M  
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Phone: 202-564-9042, Fax: 202-564-9490

---

**From:** Berger, Tom C. <Berger@khlaw.com>  
**Sent:** Wednesday, April 08, 2020 10:48 AM  
**To:** Schweer, Greg <Schweer.Greg@epa.gov>  
**Cc:** Daniels, Rhys G. <daniels@khlaw.com>; Bauer, Jeff <Bauer.Jeff@epa.gov>; Price, Amanda <price@khlaw.com>  
**Subject:** RE: **Ex. 4 CBI**

Hi Greg –

I was just going through my to-do list and thought I would circle back on these two cases. I hope everyone is hanging in there.

Thanks again – Tom

---

**From:** Berger, Tom C.  
**Sent:** Monday, March 30, 2020 3:46 PM  
**To:** Schweer, Greg <Schweer.Greg@epa.gov>  
**Cc:** Daniels, Rhys G. <daniels@khlaw.com>; Bauer, Jeff <Bauer.Jeff@epa.gov>; Price, Amanda <price@khlaw.com>  
**Subject:** RE: **Ex. 4 CBI**

Greg / all – completely understood – thank you so much.

Tom

---

**From:** Schweer, Greg <Schweer.Greg@epa.gov>  
**Sent:** Monday, March 30, 2020 3:42 PM  
**To:** Berger, Tom C. <Berger@khlaw.com>  
**Cc:** Daniels, Rhys G. <daniels@khlaw.com>; Bauer, Jeff <Bauer.Jeff@epa.gov>  
**Subject:** RE: **Ex. 4 CBI**

Hi Tom.

I am not ignoring you. I did check with Jeff Bauer early last week on this case. He filled me in on the requests he had made of RAD to review submitted test data and your request for a meeting. However, believe it or not, we have been having issues reliably being able to access our CBI-secure LAN. This hampers our ability to efficiently complete work. I will check on the status of your case as soon as I can.

---

**From:** Berger, Tom C. <Berger@khlaw.com>  
**Sent:** Monday, March 30, 2020 11:51 AM  
**To:** Schweer, Greg <Schweer.Greg@epa.gov>  
**Cc:** Daniels, Rhys G. <daniels@khlaw.com>  
**Subject:** RE: **Ex. 4 CBI**

Hi Greg –

Hope all is well.

Just thought I would check in with you on the **Ex. 4 CBI** LVEA (Lauren Davis) and **Ex. 4 CBI** **Ex. 4 CBI** with Jeff Bauer.

Thanks all always - Tom

---

**From:** Berger, Tom C.  
**Sent:** Tuesday, March 24, 2020 11:12 AM  
**To:** Schweer, Greg <Schweer.Greg@epa.gov>  
**Cc:** Daniels, Rhys G. <daniels@khlaw.com>  
**Subject:** RE: **Ex. 4 CBI**

Greg – thanks so much as always. I also have an LVE with Lauren Davis **Ex. 4 CBI** held up in the process. Lauren has been responsive but the case has stalled (again, however, I understand the challenges you are facing).

These are my two “priority” cases.



Tom

---

**From:** Schweer, Greg <Schweer.Greg@epa.gov>  
**Sent:** Tuesday, March 24, 2020 11:07 AM  
**To:** Berger, Tom C. <Berger@khlaw.com>  
**Cc:** Daniels, Rhys G. <daniels@khlaw.com>  
**Subject:** Re: **Ex. 4 CBI**

Tom,

Yes, things are a bit crazy. I will check into the case status today or tomorrow.

Sent from my iPhone

On Mar 24, 2020, at 10:48 AM, Berger, Tom C. <Berger@khlaw.com> wrote:

Hi Greg –

Obviously things are crazy and I don't want to push Jeff too hard but no response from Jeff on this case for a month.

Hang in there....

Tom

---

**From:** Berger, Tom C.  
**Sent:** Monday, March 23, 2020 6:22 PM  
**To:** Bauer, Jeff <Bauer.Jeff@epa.gov>  
**Cc:** Daniels, Rhys G. <daniels@khlaw.com>  
**Subject:** RE: **Ex. 4 CBI**

Hi Jeff –

Apologies – just want to make sure you are getting these emails. Understand if there are delays.

Tom

---

**From:** Berger, Tom C.  
**Sent:** Thursday, March 19, 2020 5:22 PM  
**To:** Bauer, Jeff <Bauer.Jeff@epa.gov>  
**Cc:** Daniels, Rhys G. <daniels@khlaw.com>  
**Subject:** RE: **Ex. 4 CBI**

Hi Jeff – checking in again – thanks - Tom

---

**From:** Berger, Tom C.  
**Sent:** Monday, March 16, 2020 1:40 PM  
**To:** Bauer, Jeff <Bauer.Jeff@epa.gov>  
**Cc:** Daniels, Rhys G. <daniels@khlaw.com>  
**Subject:** RE: **Ex. 4 CBI**

Hi Jeff –

I know things are crazy but checking in again – thanks - Tom

---

**From:** Berger, Tom C.  
**Sent:** Wednesday, March 11, 2020 3:43 PM  
**To:** Bauer, Jeff <Bauer.Jeff@epa.gov>  
**Cc:** Daniels, Rhys G. <daniels@khlaw.com>  
**Subject:** RE: **Ex. 4 CBI**

Hi Jeff –

Checking in again - thanks

---

**From:** Berger, Tom C.  
**Sent:** Friday, March 6, 2020 1:33 PM  
**To:** Bauer, Jeff <Bauer.Jeff@epa.gov>  
**Cc:** Daniels, Rhys G. <daniels@khlaw.com>  
**Subject:** RE: **Ex. 4 CBI**

Hi Jeff –

The submitter is quite anxious – can we touch base next week?

Thanks much - Tom

---

**From:** Berger, Tom C.  
**Sent:** Tuesday, February 25, 2020 9:08 AM  
**To:** Bauer, Jeff <Bauer.Jeff@epa.gov>  
**Cc:** Daniels, Rhys G. <daniels@khlaw.com>  
**Subject:** RE: **Ex. 4 CBI**

Hi Jeff –

Just checking in on this – thanks - Tom

---

**From:** Berger, Tom C.  
**Sent:** Thursday, February 20, 2020 12:18 PM  
**To:** Bauer, Jeff <Bauer.Jeff@epa.gov>  
**Cc:** Daniels, Rhys G. <daniels@khlaw.com>  
**Subject:** RE: **Ex. 4 CBI**

Hi Jeff –

I hope that all is well.

Per our discussions, the submitter has modified the questions to focus on toxicity/risk issues and submitted them via CDX yesterday. Can we start looking at conference call dates the week of March 9?

Thanks and best regards,  
Tom

Thomas C. Berger  
Partner  
tel: 202.434.4285 | fax: 202.434.4646 | [berger@khlaw.com](mailto:berger@khlaw.com)  
1001 G Street, N.W., Suite 500 West | Washington, D.C. 20001

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---

**From:** Berger, Tom C.  
**Sent:** Wednesday, January 29, 2020 11:41 AM  
**To:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>  
**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>  
**Subject:** RE: **Ex. 4 CBI**

Hi Jeff –

Apologies we keep playing phone tag – can we discuss how to convert the below questions into questions that would be acceptable to RAD so we can schedule a call with you and RAD? Your voicemail suggested the below are more legal/regulatory than risk-based questions. We still need the below questions answered – perhaps we tee up the more scientific ones for RAD then have the call to address both types of questions. The submitter is under growing commercial pressure.

Thanks much again - Tom

---

**From:** Berger, Tom C.  
**Sent:** Monday, January 20, 2020 3:50 PM  
**To:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>  
**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>  
**Subject:** RE: **Ex. 4 CBI**

Hi Jeff –

Apologies that we could not connect last week. Let's try to touch base tomorrow (Tuesday) if possible to discuss how to move this forward.

Thanks again – Tom

Thomas C. Berger  
Partner  
tel: 202.434.4285 | fax: 202.434.4646 | [berger@khlaw.com](mailto:berger@khlaw.com)  
1001 G Street, N.W., Suite 500 West | Washington, D.C. 20001

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**From:** Berger, Tom C.  
**Sent:** Monday, January 13, 2020 2:50 PM  
**To:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>  
**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>  
**Subject:** RE: **Ex. 4 CBI**  
**Importance:** High

Hi Jeff –

Following is the list of questions we are considering submitting through CDX. Please let me know if these look ok.

Thanks again and best regards,  
Tom

\* \* \*

*(1) Based on review of the submitted physical-chemical properties test data, does EPA now agree that use of **Ex. 4 CBI** as described in the PMN poses no unreasonable risk of injury and so plans to revoke the consent order?*

*(2) If so, what is the process for revoking the current consent order? Does the submitter now need to request that EPA revoke the order, or will EPA itself initiate revocation? What is the expected timing for revocation? How would EPA communicate such revocation?*

*(3) How would revocation of the consent order impact the final SNUR for the subject substance?*

*(4) Would a SNUN be a more expedient approach?*

\* \* \*

---

**From:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>  
**Sent:** Wednesday, January 8, 2020 8:56 AM  
**To:** Berger, Tom C. <[Berger@khlaw.com](mailto:Berger@khlaw.com)>  
**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>  
**Subject:** RE: **Ex. 4 CBI**

Tom, I am expecting information from the engineer today or tomorrow on the **Ex. 4 CBI** test. I left you a message. There is a new procedure for us to set up meeting with RAD. I am to have the submitter send in a list of questions for RAD, they will assign someone up there as a Lead person who has two weeks and will set a date for when we can have a meeting. This may be our best route to other than just me

bugging them to get things done. There were a series of emails on this case last week but now everyone is back from the holidays I am trying to get this case moving again.

Jeff Bauer - Program Manager  
United States Environmental Protection Agency (USEPA)  
Office of Pollution Prevention and Toxics (OPPT)  
New Chemicals Program (7405M)  
<http://www.epa.gov/oppt/newchemicals/>

EPA East Building, room 4133M  
1201 Constitution Ave., NW  
Washington, DC 20004  
Phone: 202-564-9042, Fax: 202-564-9490

---

**From:** Berger, Tom C. <[Berger@khlaw.com](mailto:Berger@khlaw.com)>  
**Sent:** Tuesday, January 07, 2020 4:16 PM  
**To:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>  
**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>  
**Subject:** RE: **Ex. 4 CBI**

Hi Jeff –

I hope you had a great holiday! The client was wondering if we could have a conference call on this, this week or next. Please advise.

Thanks much – Tom

Thomas C. Berger  
Partner  
tel: 202.434.4285 | fax: 202.434.4646 | [berger@khlaw.com](mailto:berger@khlaw.com)  
1001 G Street, N.W., Suite 500 West | Washington, D.C. 20001

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**From:** Berger, Tom C.  
**Sent:** Tuesday, December 10, 2019 2:10 PM  
**To:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>  
**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>  
**Subject:** RE: **Ex. 4 CBI**

Hi Jeff –

Just checking back in – thanks - Tom

---

**From:** Berger, Tom C.  
**Sent:** Thursday, December 5, 2019 9:46 AM  
**To:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>  
**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>  
**Subject:** RE: **Ex. 4 CBI**

Hi Jeff –

When we spoke before Thanksgiving (I hope you had a great one!) you indicated that the reports were being reviewed and that I should reach out to you in early December.

Is there any update?

Thanks much and best regards – Tom

Thomas C. Berger  
Partner  
tel: 202.434.4285 | fax: 202.434.4646 | [berger@khlaw.com](mailto:berger@khlaw.com)  
1001 G Street, N.W., Suite 500 West | Washington, D.C. 20001

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**From:** Berger, Tom C.  
**Sent:** Monday, November 18, 2019 1:17 PM  
**To:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>  
**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>  
**Subject:** RE: **Ex. 4 CBI**

Hi Jeff –

The PMN submitter asked me to reach out to you to see if we can schedule a conference call (including EPA, K&H, and the submitter) on this case re status and pathforward.

Thanks - Tom

---

**From:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>  
**Sent:** Friday, March 29, 2019 5:43 PM  
**To:** Berger, Tom C. <[Berger@khlaw.com](mailto:Berger@khlaw.com)>; Schweer, Greg <[Schweer.Greg@epa.gov](mailto:Schweer.Greg@epa.gov)>  
**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>  
**Subject:** RE: **Ex. 4 CBI**

Tom,  
I set the meeting up for Wednesday April 3, at 11 am. RAD has accepted the invitation for that time.

Jeff Bauer - Program Manager  
United States Environmental Protection Agency (USEPA)  
Office of Pollution Prevention and Toxics (OPPT)  
New Chemicals Program (7405M)  
<http://www.epa.gov/oppt/newchems/>

EPA East Building, room 4133M  
1201 Constitution Ave., NW  
Washington, DC 20004  
Phone: 202-564-9042, Fax: 202-564-9490

---

**From:** Bauer, Jeff  
**Sent:** Tuesday, March 26, 2019 11:37 AM  
**To:** 'Berger, Tom C.' <[Berger@khlaw.com](mailto:Berger@khlaw.com)>; Schweer, Greg <[Schweer.Greg@epa.gov](mailto:Schweer.Greg@epa.gov)>  
**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>  
**Subject:** RE: **Ex. 4 CBI**

Tom, I left you a voice message, I am seeing what time it best for RAD to be part of the call.

Jeff Bauer - Program Manager  
United States Environmental Protection Agency (USEPA)  
Office of Pollution Prevention and Toxics (OPPT)  
New Chemicals Program (7405M)  
<http://www.epa.gov/oppt/newchems/>

EPA East Building, room 4133M  
1201 Constitution Ave., NW  
Washington, DC 20004  
Phone: 202-564-9042, Fax: 202-564-9490

---

**From:** Berger, Tom C. <[Berger@khlaw.com](mailto:Berger@khlaw.com)>  
**Sent:** Tuesday, March 26, 2019 11:30 AM  
**To:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>; Schweer, Greg <[Schweer.Greg@epa.gov](mailto:Schweer.Greg@epa.gov)>  
**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>  
**Subject:** RE: **Ex. 4 CBI**

Hi folks –

Just thought I would check in with you on this.

Thanks again - Tom

---

**From:** Berger, Tom C.  
**Sent:** Friday, March 22, 2019 2:12 PM  
**To:** 'Bauer.jeff@Epa.gov' <[Bauer.jeff@Epa.gov](mailto:Bauer.jeff@Epa.gov)>; 'Schweer, Greg' <[Schweer.Greg@epa.gov](mailto:Schweer.Greg@epa.gov)>  
**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>  
**Subject:** **Ex. 4 CBI**

Hi folks –

I hope you are doing well. Jeff – this is the PMN case that my colleague, Dr. Rhys Daniels, spoke with you about earlier this week.

The issue is development of data needed to amend the existing section 5(e) order for this substance to add an additional use, and EPA approval of protocols for same. Would the Agency be available for a short conference call on this on one of the following days?:

- March 27 (except 12-2 ET)
- April 2
- April 3
- April 4

This is becoming more urgent from a commercial standpoint.

Thanks much - Tom

Thomas C. Berger

Partner

tel: 202.434.4285 | fax: 202.434.4646 | [berger@khlaw.com](mailto:berger@khlaw.com)

1001 G Street, N.W., Suite 500 West | Washington, D.C. 20001

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Message

**From:** Daniels, Rhys G. [daniels@khlaw.com]  
**Sent:** 4/21/2020 8:57:42 PM  
**To:** Bauer, Jeff [Bauer.Jeff@epa.gov]; Berger, Tom C. [Berger@khlaw.com]  
**CC:** Price, Amanda [price@khlaw.com]; Schweer, Greg [Schweer.Greg@epa.gov]  
**Subject:** RE: **Ex. 4 CBI**  
**Attachments:** ATT00001.txt

Jeff,

As always, we hope that all is well.

Per your recent voicemail and follow-up email concerning the **Ex. 4 CBI** case, we understand that the chemist has two questions concerning **Ex. 4 CBI**

**Ex. 4 CBI**

Thanks in advance for your response.

Rhys G. Daniels, Ph.D.  
Staff Scientist  
tel: +1 202.434.4270 | fax: +1 202.434.4646 | [daniels@khlaw.com](mailto:daniels@khlaw.com)  
1001 G Street NW, Suite 500 West | Washington, DC 20001

---

**From:** Bauer, Jeff <Bauer.Jeff@epa.gov>  
**Sent:** Thursday, April 16, 2020 1:02 PM  
**To:** Berger, Tom C. <Berger@khlaw.com>  
**Cc:** Daniels, Rhys G. <daniels@khlaw.com>; Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>  
**Subject:** RE: **Ex. 4 CBI**

Tom,

The chemist sent me a memo **Ex. 4 CBI** and they had two questions, I called and left you a message today **Ex. 4 CBI** I sent RAD a request last week to update the HH assessment **Ex. 4 CBI** **Ex. 4 CBI** as in my April 4, 2020 email to you. I have two emails into RAD on this case and will try an update you again in a week or so. I requested RAD set up a date with me to have a meeting to discuss how to proceed with this PMN.

Thanks  
Jeff

Jeff Bauer - Program Manager  
United States Environmental Protection Agency (USEPA)  
Office of Pollution Prevention and Toxics (OPPT)  
New Chemicals Program (7405M)  
<http://www.epa.gov/oppt/newchemicals/>

EPA East Building, room 4133M  
1201 Constitution Ave., NW  
Washington, DC 20004  
Phone: 202-564-9042, Fax: 202-564-9490

---

**From:** Berger, Tom C. <Berger@khlaw.com>  
**Sent:** Thursday, April 16, 2020 12:28 PM  
**To:** Bauer, Jeff <Bauer.Jeff@epa.gov>  
**Cc:** Daniels, Rhys G. <daniels@khlaw.com>; Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>  
**Subject:** RE: **Ex. 4 CBI**

Hi Jeff –

I hope that all is well.

Just checking in re status update. A non-CBI-containing email from you would probably be the best (if needed at some later time we can use EPA's new CBI via email authorization form if the submitter agrees).

Thanks again – Tom

---

**From:** Berger, Tom C.  
**Sent:** Wednesday, April 8, 2020 11:06 AM  
**To:** Bauer, Jeff <Bauer.Jeff@epa.gov>; Schweer, Greg <Schweer.Greg@epa.gov>  
**Cc:** Daniels, Rhys G. <daniels@khlaw.com>; Price, Amanda <price@khlaw.com>  
**Subject:** RE: **Ex. 4 CBI**

Jeff – thanks much for the update. Hope you and all at EPA are staying safe.

Tom

---

**From:** Bauer, Jeff <Bauer.Jeff@epa.gov>  
**Sent:** Wednesday, April 8, 2020 11:03 AM  
**To:** Berger, Tom C. <Berger@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>  
**Cc:** Daniels, Rhys G. <daniels@khlaw.com>; Price, Amanda <price@khlaw.com>  
**Subject:** RE: **Ex. 4 CBI**

Tom,

## Ex. 4 CBI

## Ex. 4 CBI

I will follow up with you next wed with a status update.

Jeff Bauer - Program Manager  
United States Environmental Protection Agency (USEPA)  
Office of Pollution Prevention and Toxics (OPPT)  
New Chemicals Program (7405M)  
<http://www.epa.gov/oppt/newchemicals/>

EPA East Building, room 4133M  
1201 Constitution Ave., NW  
Washington, DC 20004  
Phone: 202-564-9042, Fax: 202-564-9490

---

**From:** Berger, Tom C. <[Berger@khlaw.com](mailto:Berger@khlaw.com)>  
**Sent:** Wednesday, April 08, 2020 10:48 AM  
**To:** Schweer, Greg <[Schweer.Greg@epa.gov](mailto:Schweer.Greg@epa.gov)>  
**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>; Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>; Price, Amanda <[price@khlaw.com](mailto:price@khlaw.com)>  
**Subject:** RE: **Ex. 4 CBI**

Hi Greg –

I was just going through my to-do list and thought I would circle back on these two cases. I hope everyone is hanging in there.

Thanks again – Tom

---

**From:** Berger, Tom C.  
**Sent:** Monday, March 30, 2020 3:46 PM  
**To:** Schweer, Greg <[Schweer.Greg@epa.gov](mailto:Schweer.Greg@epa.gov)>  
**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>; Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>; Price, Amanda <[price@khlaw.com](mailto:price@khlaw.com)>  
**Subject:** RE: **Ex. 4 CBI**

Greg / all – completely understood – thank you so much.

Tom

---

**From:** Schweer, Greg <[Schweer.Greg@epa.gov](mailto:Schweer.Greg@epa.gov)>  
**Sent:** Monday, March 30, 2020 3:42 PM  
**To:** Berger, Tom C. <[Berger@khlaw.com](mailto:Berger@khlaw.com)>  
**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>; Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>  
**Subject:** RE: **Ex. 4 CBI**

Hi Tom.

I am not ignoring you. I did check with Jeff Bauer early last week on this case. He filled me in on the requests he had made of RAD to review submitted test data and your request for a meeting. However, believe it or not, we have been having issues reliably being able to access our CBI-secure LAN. This hampers our ability to efficiently complete work. I will check on the status of your case as soon as I can.

---

**From:** Berger, Tom C. <Berger@khlaw.com>  
**Sent:** Monday, March 30, 2020 11:51 AM  
**To:** Schweer, Greg <Schweer.Greg@epa.gov>  
**Cc:** Daniels, Rhys G. <daniels@khlaw.com>  
**Subject:** RE: Ex. 4 CBI

Hi Greg –

Hope all is well.

Just thought I would check in with you on the Ex. 4 CBI LVEA (Lauren Davis) and Ex. 4 CBI with Jeff Bauer.

Thanks all always - Tom

---

**From:** Berger, Tom C.  
**Sent:** Tuesday, March 24, 2020 11:12 AM  
**To:** Schweer, Greg <Schweer.Greg@epa.gov>  
**Cc:** Daniels, Rhys G. <daniels@khlaw.com>  
**Subject:** RE: Ex. 4 CBI

Greg – thanks so much as always. I also have an LVE with Lauren Davis Ex. 4 CBI held up in the process. Lauren has been responsive but the case has stalled (again, however, I understand the challenges you are facing).

These are my two “priority” cases.

Tom

---

**From:** Schweer, Greg <Schweer.Greg@epa.gov>  
**Sent:** Tuesday, March 24, 2020 11:07 AM  
**To:** Berger, Tom C. <Berger@khlaw.com>  
**Cc:** Daniels, Rhys G. <daniels@khlaw.com>  
**Subject:** Re: Ex. 4 CBI

Tom,

Yes, things are a bit crazy. I will check into the case status today or tomorrow.

Sent from my iPhone

On Mar 24, 2020, at 10:48 AM, Berger, Tom C. <Berger@khlaw.com> wrote:

Hi Greg –

Obviously things are crazy and I don't want to push Jeff too hard but no response from Jeff on this case for a month.

Hang in there....

Tom

---

**From:** Berger, Tom C.  
**Sent:** Monday, March 23, 2020 6:22 PM  
**To:** Bauer, Jeff <Bauer.Jeff@epa.gov>  
**Cc:** Daniels, Rhys G. <daniels@khlaw.com>  
**Subject:** RE: **Ex. 4 CBI**

Hi Jeff –

Apologies – just want to make sure you are getting these emails. Understand if there are delays.

Tom

---

**From:** Berger, Tom C.  
**Sent:** Thursday, March 19, 2020 5:22 PM  
**To:** Bauer, Jeff <Bauer.Jeff@epa.gov>  
**Cc:** Daniels, Rhys G. <daniels@khlaw.com>  
**Subject:** RE: **Ex. 4 CBI**

Hi Jeff – checking in again – thanks - Tom

---

**From:** Berger, Tom C.  
**Sent:** Monday, March 16, 2020 1:40 PM  
**To:** Bauer, Jeff <Bauer.Jeff@epa.gov>  
**Cc:** Daniels, Rhys G. <daniels@khlaw.com>  
**Subject:** RE: **Ex. 4 CBI**

Hi Jeff –

I know things are crazy but checking in again – thanks - Tom

---

**From:** Berger, Tom C.  
**Sent:** Wednesday, March 11, 2020 3:43 PM  
**To:** Bauer, Jeff <Bauer.Jeff@epa.gov>  
**Cc:** Daniels, Rhys G. <daniels@khlaw.com>  
**Subject:** RE: **Ex. 4 CBI**

Hi Jeff –

Checking in again - thanks

---

**From:** Berger, Tom C.  
**Sent:** Friday, March 6, 2020 1:33 PM  
**To:** Bauer, Jeff <Bauer.Jeff@epa.gov>  
**Cc:** Daniels, Rhys G. <daniels@khlaw.com>  
**Subject:** RE: **Ex. 4 CBI**

Hi Jeff –

The submitter is quite anxious – can we touch base next week?

Thanks much - Tom

---

**From:** Berger, Tom C.  
**Sent:** Tuesday, February 25, 2020 9:08 AM  
**To:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>  
**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>  
**Subject:** RE: **Ex. 4 CBI**

Hi Jeff –

Just checking in on this – thanks - Tom

---

**From:** Berger, Tom C.  
**Sent:** Thursday, February 20, 2020 12:18 PM  
**To:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>  
**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>  
**Subject:** RE: **Ex. 4 CBI**

Hi Jeff –

I hope that all is well.

Per our discussions, the submitter has modified the questions to focus on toxicity/risk issues and submitted them via CDX yesterday. Can we start looking at conference call dates the week of March 9?

Thanks and best regards,  
Tom

Thomas C. Berger  
Partner  
tel: 202.434.4285 | fax: 202.434.4646 | [berger@khlaw.com](mailto:berger@khlaw.com)  
1001 G Street, N.W., Suite 500 West | Washington, D.C. 20001

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**From:** Berger, Tom C.  
**Sent:** Wednesday, January 29, 2020 11:41 AM  
**To:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>  
**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>  
**Subject:** RE: **Ex. 4 CBI**

Hi Jeff –

Apologies we keep playing phone tag – can we discuss how to convert the below questions into questions that would be acceptable to RAD so we can schedule a call with you and RAD? Your voicemail suggested the below are more legal/regulatory than risk-based questions. We still need the below questions answered – perhaps we tee up the more scientific ones for RAD then have the call to address both types of questions. The submitter is under growing commercial pressure.

Thanks much again - Tom

---

**From:** Berger, Tom C.  
**Sent:** Monday, January 20, 2020 3:50 PM  
**To:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>  
**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>  
**Subject:** RE: **Ex. 4 CBI**

Hi Jeff –

Apologies that we could not connect last week. Let's try to touch base tomorrow (Tuesday) if possible to discuss how to move this forward.

Thanks again – Tom

Thomas C. Berger  
Partner  
tel: 202.434.4285 | fax: 202.434.4646 | [berger@khlaw.com](mailto:berger@khlaw.com)  
1001 G Street, N.W., Suite 500 West | Washington, D.C. 20001

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**From:** Berger, Tom C.  
**Sent:** Monday, January 13, 2020 2:50 PM  
**To:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>  
**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>  
**Subject:** RE: **Ex. 4 CBI**  
**Importance:** High

Hi Jeff –

Following is the list of questions we are considering submitting through CDX. Please let me know if these look ok.

Thanks again and best regards,  
Tom

\* \* \*

(1) Based on review of the submitted physical-chemical properties test data, does EPA now agree that use **Ex. 4 CBI** as described in the PMN poses no unreasonable risk of injury and so plans to revoke the consent order?

(2) If so, what is the process for revoking the current consent order? Does the submitter now need to request that EPA revoke the order, or will EPA itself initiate revocation? What is the expected timing for revocation? How would EPA communicate such revocation?

(3) How would revocation of the consent order impact the final SNUR for the subject substance?

(4) Would a SNUN be a more expedient approach?

\* \* \*

---

**From:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>  
**Sent:** Wednesday, January 8, 2020 8:56 AM  
**To:** Berger, Tom C. <[Berger@khlaw.com](mailto:Berger@khlaw.com)>  
**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>  
**Subject:** RE: **Ex. 4 CBI**

Tom, I am expecting information from the engineer today or tomorrow on the **Ex. 4 CBI** test, I left you a message. There is a new procedure for us to set up meeting with RAD. I am to have the submitter send in a list of questions for RAD, they will assign someone up there as a Lead person who has two weeks and will set a date for when we can have a meeting. This may be our best route to other than just me bugging them to get things done. There were a series of emails on this case last week but now everyone is back from the holidays I am trying to get this case moving again.

Jeff Bauer - Program Manager  
United States Environmental Protection Agency (USEPA)  
Office of Pollution Prevention and Toxics (OPPT)  
New Chemicals Program (7405M)  
<http://www.epa.gov/oppt/newchemicals/>

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Phone: 202-564-9042, Fax: 202-564-9490

---

**From:** Berger, Tom C. <[Berger@khlaw.com](mailto:Berger@khlaw.com)>  
**Sent:** Tuesday, January 07, 2020 4:16 PM  
**To:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>  
**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>  
**Subject:** RE: **Ex. 4 CBI**

Hi Jeff –

I hope you had a great holiday! The client was wondering if we could have a conference call on this, this week or next. Please advise.



Thanks much – Tom

Thomas C. Berger

Partner

tel: 202.434.4285 | fax: 202.434.4646 | [berger@khlaw.com](mailto:berger@khlaw.com)

1001 G Street, N.W., Suite 500 West | Washington, D.C. 20001

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**From:** Berger, Tom C.

**Sent:** Tuesday, December 10, 2019 2:10 PM

**To:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>

**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>

**Subject:** RE: **Ex. 4 CBI**

Hi Jeff –

Just checking back in – thanks - Tom

---

**From:** Berger, Tom C.

**Sent:** Thursday, December 5, 2019 9:46 AM

**To:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>

**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>

**Subject:** RE: **Ex. 4 CBI**

Hi Jeff –

When we spoke before Thanksgiving (I hope you had a great one!) you indicated that the reports were being reviewed and that I should reach out to you in early December.

Is there any update?

Thanks much and best regards – Tom

Thomas C. Berger

Partner

tel: 202.434.4285 | fax: 202.434.4646 | [berger@khlaw.com](mailto:berger@khlaw.com)

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---

**From:** Berger, Tom C.  
**Sent:** Monday, November 18, 2019 1:17 PM  
**To:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>  
**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>  
**Subject:** RE: **Ex. 4 CBI**

Hi Jeff –

The PMN submitter asked me to reach out to you to see if we can schedule a conference call (including EPA, K&H, and the submitter) on this case re status and pathforward.

Thanks - Tom

---

**From:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>  
**Sent:** Friday, March 29, 2019 5:43 PM  
**To:** Berger, Tom C. <[Berger@khlaw.com](mailto:Berger@khlaw.com)>; Schweer, Greg <[Schweer.Greg@epa.gov](mailto:Schweer.Greg@epa.gov)>  
**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>  
**Subject:** RE: **Ex. 4 CBI**

Tom,  
I set the meeting up for Wednesday April 3, at 11 am. RAD has accepted the invitation for that time.

Jeff Bauer - Program Manager  
United States Environmental Protection Agency (USEPA)  
Office of Pollution Prevention and Toxics (OPPT)  
New Chemicals Program (7405M)  
<http://www.epa.gov/oppt/newchems/>

EPA East Building, room 4133M  
1201 Constitution Ave., NW  
Washington, DC 20004  
Phone: 202-564-9042, Fax: 202-564-9490

---

**From:** Bauer, Jeff  
**Sent:** Tuesday, March 26, 2019 11:37 AM  
**To:** 'Berger, Tom C.' <[Berger@khlaw.com](mailto:Berger@khlaw.com)>; Schweer, Greg <[Schweer.Greg@epa.gov](mailto:Schweer.Greg@epa.gov)>  
**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>  
**Subject:** RE: **Ex. 4 CBI**

Tom, I left you a voice message, I am seeing what time it best for RAD to be part of the call.

Jeff Bauer - Program Manager  
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**From:** Berger, Tom C. <Berger@khlaw.com>  
**Sent:** Tuesday, March 26, 2019 11:30 AM  
**To:** Bauer, Jeff <Bauer.Jeff@epa.gov>; Schweer, Greg <Schweer.Greg@epa.gov>  
**Cc:** Daniels, Rhys G. <daniels@khlaw.com>  
**Subject:** RE: **Ex. 4 CBI**

Hi folks –

Just thought I would check in with you on this.

Thanks again - Tom

---

**From:** Berger, Tom C.  
**Sent:** Friday, March 22, 2019 2:12 PM  
**To:** 'Bauer.jeff@Epa.gov' <Bauer.jeff@Epa.gov>; 'Schweer, Greg' <Schweer.Greg@epa.gov>  
**Cc:** Daniels, Rhys G. <daniels@khlaw.com>  
**Subject:** **Ex. 4 CBI**

Hi folks –

I hope you are doing well. Jeff – this is the PMN case that my colleague, Dr. Rhys Daniels, spoke with you about earlier this week.

The issue is development of data needed to amend the existing section 5(e) order for this substance to add an additional use, and EPA approval of protocols for same. Would the Agency be available for a short conference call on this on one of the following days?:

- March 27 (except 12-2 ET)
- April 2
- April 3
- April 4

This is becoming more urgent from a commercial standpoint.

Thanks much - Tom

Thomas C. Berger  
Partner  
tel: 202.434.4285 | fax: 202.434.4646 | [berger@khlaw.com](mailto:berger@khlaw.com)  
1001 G Street, N.W., Suite 500 West | Washington, D.C. 20001

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Message

---

**From:** Bauer, Jeff [Bauer.Jeff@epa.gov]  
**Sent:** 4/16/2020 5:02:29 PM  
**To:** Berger, Tom C. [Berger@khlaw.com]  
**CC:** Daniels, Rhys G. [daniels@khlaw.com]; Price, Amanda [price@khlaw.com]; Schweer, Greg [Schweer.Greg@epa.gov]  
**Subject:** RE: **Ex. 4 CBI**

Tom,

The chemist sent me a memo **Ex. 4 CBI** and they had two questions, I called and left you a message today **Ex. 4 CBI**. I sent RAD a request last week to update the HH assessment **Ex. 4 CBI** **Ex. 4 CBI** as in my April 4, 2020 email to you. I have two emails into RAD on this case and will try an update you again in a week or so. I requested RAD set up a date with me to have a meeting to discuss how to proceed with this PMN.

Thanks  
Jeff

Jeff Bauer - Program Manager  
United States Environmental Protection Agency (USEPA)  
Office of Pollution Prevention and Toxics (OPPT)  
New Chemicals Program (7405M)  
<http://www.epa.gov/oppt/newchems/>

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Washington, DC 20004  
Phone: 202-564-9042, Fax: 202-564-9490

---

**From:** Berger, Tom C. <Berger@khlaw.com>  
**Sent:** Thursday, April 16, 2020 12:28 PM  
**To:** Bauer, Jeff <Bauer.Jeff@epa.gov>  
**Cc:** Daniels, Rhys G. <daniels@khlaw.com>; Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>  
**Subject:** RE: **Ex. 4 CBI**

Hi Jeff –

I hope that all is well.

Just checking in re status update. A non-CBI-containing email from you would probably be the best (if needed at some later time we can use EPA's new CBI via email authorization form if the submitter agrees).

Thanks again – Tom

---

**From:** Berger, Tom C.  
**Sent:** Wednesday, April 8, 2020 11:06 AM  
**To:** Bauer, Jeff <Bauer.Jeff@epa.gov>; Schweer, Greg <Schweer.Greg@epa.gov>

**Cc:** Daniels, Rhys G. <daniels@khlaw.com>; Price, Amanda <price@khlaw.com>

**Subject:** RE: **Ex. 4 CBI**

Jeff – thanks much for the update. Hope you and all at EPA are staying safe.

Tom

---

**From:** Bauer, Jeff <Bauer.Jeff@epa.gov>

**Sent:** Wednesday, April 8, 2020 11:03 AM

**To:** Berger, Tom C. <Berger@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>

**Cc:** Daniels, Rhys G. <daniels@khlaw.com>; Price, Amanda <price@khlaw.com>

**Subject:** RE: **Ex. 4 CBI**

Tom,

# Ex. 4 CBI

I will follow up with you next wed with a status update.

Jeff Bauer - Program Manager  
United States Environmental Protection Agency (USEPA)  
Office of Pollution Prevention and Toxics (OPPT)  
New Chemicals Program (7405M)  
<http://www.epa.gov/oppt/newchemicals/>

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1201 Constitution Ave., NW  
Washington, DC 20004  
Phone: 202-564-9042, Fax: 202-564-9490

---

**From:** Berger, Tom C. <Berger@khlaw.com>

**Sent:** Wednesday, April 08, 2020 10:48 AM

**To:** Schweer, Greg <Schweer.Greg@epa.gov>

**Cc:** Daniels, Rhys G. <daniels@khlaw.com>; Bauer, Jeff <Bauer.Jeff@epa.gov>; Price, Amanda <price@khlaw.com>

**Subject:** RE: **Ex. 4 CBI**

Hi Greg –

I was just going through my to-do list and thought I would circle back on these two cases. I hope everyone is hanging in there.

Thanks again – Tom

---

**From:** Berger, Tom C.

**Sent:** Monday, March 30, 2020 3:46 PM

**To:** Schweer, Greg <Schweer.Greg@epa.gov>

**Cc:** Daniels, Rhys G. <daniels@khlaw.com>; Bauer, Jeff <Bauer.Jeff@epa.gov>; Price, Amanda <price@khlaw.com>

**Subject:** RE: **Ex. 4 CBI**

Greg / all – completely understood – thank you so much.

Tom

---

**From:** Schweer, Greg <Schweer.Greg@epa.gov>  
**Sent:** Monday, March 30, 2020 3:42 PM  
**To:** Berger, Tom C. <Berger@khlaw.com>  
**Cc:** Daniels, Rhys G. <daniels@khlaw.com>; Bauer, Jeff <Bauer.Jeff@epa.gov>  
**Subject:** RE: Ex. 4 CBI

Hi Tom.

I am not ignoring you. I did check with Jeff Bauer early last week on this case. He filled me in on the requests he had made of RAD to review submitted test data and your request for a meeting. However, believe it or not, we have been having issues reliably being able to access our CBI-secure LAN. This hampers our ability to efficiently complete work. I will check on the status of your case as soon as I can.

---

**From:** Berger, Tom C. <Berger@khlaw.com>  
**Sent:** Monday, March 30, 2020 11:51 AM  
**To:** Schweer, Greg <Schweer.Greg@epa.gov>  
**Cc:** Daniels, Rhys G. <daniels@khlaw.com>  
**Subject:** RE: Ex. 4 CBI

Hi Greg –

Hope all is well.

Just thought I would check in with you on the Ex. 4 CBI LVEA (Lauren Davis) and Ex. 4 CBI with Jeff Bauer.

Thanks all always - Tom

---

**From:** Berger, Tom C.  
**Sent:** Tuesday, March 24, 2020 11:12 AM  
**To:** Schweer, Greg <Schweer.Greg@epa.gov>  
**Cc:** Daniels, Rhys G. <daniels@khlaw.com>  
**Subject:** RE: Ex. 4 CBI

Greg – thanks so much as always. I also have an LVE with Lauren Davis Ex. 4 CBI held up in the process. Lauren has been responsive but the case has stalled (again, however, I understand the challenges you are facing).

These are my two “priority” cases.

Tom

---

**From:** Schweer, Greg <Schweer.Greg@epa.gov>  
**Sent:** Tuesday, March 24, 2020 11:07 AM  
**To:** Berger, Tom C. <Berger@khlaw.com>  
**Cc:** Daniels, Rhys G. <daniels@khlaw.com>  
**Subject:** Re: Ex. 4 CBI

Tom,

Yes, things are a bit crazy. I will check into the case status today or tomorrow.

Sent from my iPhone

On Mar 24, 2020, at 10:48 AM, Berger, Tom C. <Berger@khlaw.com> wrote:

Hi Greg –

Obviously things are crazy and I don't want to push Jeff too hard but no response from Jeff on this case for a month.

Hang in there....

Tom

---

**From:** Berger, Tom C.  
**Sent:** Monday, March 23, 2020 6:22 PM  
**To:** Bauer, Jeff <Bauer.Jeff@epa.gov>  
**Cc:** Daniels, Rhys G. <daniels@khlaw.com>  
**Subject:** RE: **Ex. 4 CBI**

Hi Jeff –

Apologies – just want to make sure you are getting these emails. Understand if there are delays.

Tom

---

**From:** Berger, Tom C.  
**Sent:** Thursday, March 19, 2020 5:22 PM  
**To:** Bauer, Jeff <Bauer.Jeff@epa.gov>  
**Cc:** Daniels, Rhys G. <daniels@khlaw.com>  
**Subject:** RE: **Ex. 4 CBI**

Hi Jeff – checking in again – thanks - Tom

---

**From:** Berger, Tom C.  
**Sent:** Monday, March 16, 2020 1:40 PM  
**To:** Bauer, Jeff <Bauer.Jeff@epa.gov>  
**Cc:** Daniels, Rhys G. <daniels@khlaw.com>  
**Subject:** RE: **Ex. 4 CBI**

Hi Jeff –

I know things are crazy but checking in again – thanks - Tom

---

**From:** Berger, Tom C.  
**Sent:** Wednesday, March 11, 2020 3:43 PM



**To:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>  
**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>  
**Subject:** RE: **Ex. 4 CBI**

Hi Jeff –

Checking in again - thanks

---

**From:** Berger, Tom C.  
**Sent:** Friday, March 6, 2020 1:33 PM  
**To:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>  
**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>  
**Subject:** RE: **Ex. 4 CBI**

Hi Jeff –

The submitter is quite anxious – can we touch base next week?

Thanks much - Tom

---

**From:** Berger, Tom C.  
**Sent:** Tuesday, February 25, 2020 9:08 AM  
**To:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>  
**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>  
**Subject:** RE: **Ex. 4 CBI**

Hi Jeff –

Just checking in on this – thanks - Tom

---

**From:** Berger, Tom C.  
**Sent:** Thursday, February 20, 2020 12:18 PM  
**To:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>  
**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>  
**Subject:** RE: **Ex. 4 CBI**

Hi Jeff –

I hope that all is well.

Per our discussions, the submitter has modified the questions to focus on toxicity/risk issues and submitted them via CDX yesterday. Can we start looking at conference call dates the week of March 9?

Thanks and best regards,  
Tom

Thomas C. Berger  
Partner  
tel: 202.434.4285 | fax: 202.434.4646 | [berger@khlaw.com](mailto:berger@khlaw.com)  
1001 G Street, N.W., Suite 500 West | Washington, D.C. 20001

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**From:** Berger, Tom C.  
**Sent:** Wednesday, January 29, 2020 11:41 AM  
**To:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>  
**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>  
**Subject:** RE: **Ex. 4 CBI**

Hi Jeff –

Apologies we keep playing phone tag – can we discuss how to convert the below questions into questions that would be acceptable to RAD so we can schedule a call with you and RAD? Your voicemail suggested the below are more legal/regulatory than risk-based questions. We still need the below questions answered – perhaps we tee up the more scientific ones for RAD then have the call to address both types of questions. The submitter is under growing commercial pressure.

Thanks much again - Tom

---

**From:** Berger, Tom C.  
**Sent:** Monday, January 20, 2020 3:50 PM  
**To:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>  
**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>  
**Subject:** RE: **Ex. 4 CBI**

Hi Jeff –

Apologies that we could not connect last week. Let's try to touch base tomorrow (Tuesday) if possible to discuss how to move this forward.

Thanks again – Tom

Thomas C. Berger  
Partner  
tel: 202.434.4285 | fax: 202.434.4646 | [berger@khlaw.com](mailto:berger@khlaw.com)  
1001 G Street, N.W., Suite 500 West | Washington, D.C. 20001

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---

**From:** Berger, Tom C.  
**Sent:** Monday, January 13, 2020 2:50 PM  
**To:** Bauer, Jeff <Bauer.Jeff@epa.gov>  
**Cc:** Daniels, Rhys G. <daniels@khlaw.com>  
**Subject:** RE: Ex. 4 CBI  
**Importance:** High

Hi Jeff –

Following is the list of questions we are considering submitting through CDX. Please let me know if these look ok.

Thanks again and best regards,  
Tom

\* \* \*

*(1) Based on review of the submitted physical-chemical properties test data, does EPA now agree that use of Ex. 4 CBI as described in the PMN poses no unreasonable risk of injury and so plans to revoke the consent order?*

*(2) If so, what is the process for revoking the current consent order? Does the submitter now need to request that EPA revoke the order, or will EPA itself initiate revocation? What is the expected timing for revocation? How would EPA communicate such revocation?*

*(3) How would revocation of the consent order impact the final SNUR for the subject substance?*

*(4) Would a SNUN be a more expedient approach?*

\* \* \*

---

**From:** Bauer, Jeff <Bauer.Jeff@epa.gov>  
**Sent:** Wednesday, January 8, 2020 8:56 AM  
**To:** Berger, Tom C. <Berger@khlaw.com>  
**Cc:** Daniels, Rhys G. <daniels@khlaw.com>  
**Subject:** RE: Ex. 4 CBI

Tom, I am expecting information from the engineer today or tomorrow on the Ex. 4 CBI test, I left you a message. There is a new procedure for us to set up meeting with RAD. I am to have the submitter send in a list of questions for RAD, they will assign someone up there as a Lead person who has two weeks and will set a date for when we can have a meeting. This may be our best route to other than just me bugging them to get things done. There were a series of emails on this case last week but now everyone is back from the holidays I am trying to get this case moving again.

Jeff Bauer - Program Manager  
United States Environmental Protection Agency (USEPA)  
Office of Pollution Prevention and Toxics (OPPT)  
New Chemicals Program (7405M)

<http://www.epa.gov/oppt/newchems/>

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Phone: 202-564-9042, Fax: 202-564-9490

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**From:** Berger, Tom C. <[Berger@khlaw.com](mailto:Berger@khlaw.com)>  
**Sent:** Tuesday, January 07, 2020 4:16 PM  
**To:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>  
**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>  
**Subject:** RE: **Ex. 4 CBI**

Hi Jeff –

I hope you had a great holiday! The client was wondering if we could have a conference call on this, this week or next. Please advise.

Thanks much – Tom

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**From:** Berger, Tom C.  
**Sent:** Tuesday, December 10, 2019 2:10 PM  
**To:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>  
**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>  
**Subject:** RE: **Ex. 4 CBI**

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**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>  
**Subject:** RE: **Ex. 4 CBI**

Hi Jeff –

When we spoke before Thanksgiving (I hope you had a great one!) you indicated that the reports were being reviewed and that I should reach out to you in early December.

Is there any update?

Thanks much and best regards – Tom

Thomas C. Berger

Partner

tel: 202.434.4285 | fax: 202.434.4646 | [berger@khlaw.com](mailto:berger@khlaw.com)

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**From:** Berger, Tom C.

**Sent:** Monday, November 18, 2019 1:17 PM

**To:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>

**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>

**Subject:** RE: **Ex. 4 CBI**

Hi Jeff –

The PMN submitter asked me to reach out to you to see if we can schedule a conference call (including EPA, K&H, and the submitter) on this case re status and pathforward.

Thanks - Tom

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**Sent:** Friday, March 29, 2019 5:43 PM

**To:** Berger, Tom C. <[Berger@khlaw.com](mailto:Berger@khlaw.com)>; Schweer, Greg <[Schweer.Greg@epa.gov](mailto:Schweer.Greg@epa.gov)>

**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>

**Subject:** RE: **Ex. 4 CBI**

Tom,

I set the meeting up for Wednesday April 3, at 11 am. RAD has accepted the invitation for that time.

Jeff Bauer - Program Manager

United States Environmental Protection Agency (USEPA)

Office of Pollution Prevention and Toxics (OPPT)

New Chemicals Program (7405M)

<http://www.epa.gov/oppt/newchems/>

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Washington, DC 20004  
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**Sent:** Tuesday, March 26, 2019 11:37 AM  
**To:** 'Berger, Tom C.' <Berger@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>  
**Cc:** Daniels, Rhys G. <daniels@khlaw.com>  
**Subject:** RE: **Ex. 4 CBI**

Tom, I left you a voice message, I am seeing what time it best for RAD to be part of the call.

Jeff Bauer - Program Manager  
United States Environmental Protection Agency (USEPA)  
Office of Pollution Prevention and Toxics (OPPT)  
New Chemicals Program (7405M)  
<http://www.epa.gov/oppt/newchemicals/>

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**Sent:** Tuesday, March 26, 2019 11:30 AM  
**To:** Bauer, Jeff <Bauer.Jeff@epa.gov>; Schweer, Greg <Schweer.Greg@epa.gov>  
**Cc:** Daniels, Rhys G. <daniels@khlaw.com>  
**Subject:** RE: **Ex. 4 CBI**

Hi folks –

Just thought I would check in with you on this.

Thanks again - Tom

---

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**To:** 'Bauer.jeff@Epa.gov' <Bauer.jeff@Epa.gov>; 'Schweer, Greg' <Schweer.Greg@epa.gov>  
**Cc:** Daniels, Rhys G. <daniels@khlaw.com>  
**Subject:** **Ex. 4 CBI**

Hi folks –

I hope you are doing well. Jeff – this is the PMN case that my colleague, Dr. Rhys Daniels, spoke with you about earlier this week.

The issue is development of data needed to amend the existing section 5(e) order for this substance to add an additional use, and EPA approval of protocols for same. Would the Agency be available for a short conference call on this on one of the following days?:

- March 27 (except 12-2 ET)

- April 2
- April 3
- April 4

This is becoming more urgent from a commercial standpoint.

Thanks much - Tom

Thomas C. Berger

Partner

tel: 202.434.4285 | fax: 202.434.4646 | [berger@khlaw.com](mailto:berger@khlaw.com)

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Message

---

**From:** Berger, Tom C. [Berger@khlaw.com]  
**Sent:** 4/16/2020 4:27:59 PM  
**To:** Bauer, Jeff [Bauer.Jeff@epa.gov]  
**CC:** Daniels, Rhys G. [daniels@khlaw.com]; Price, Amanda [price@khlaw.com]; Schweer, Greg [Schweer.Greg@epa.gov]  
**Subject:** RE: **Ex. 4 CBI**

Hi Jeff –

I hope that all is well.

Just checking in re status update. A non-CBI-containing email from you would probably be the best (if needed at some later time we can use EPA's new CBI via email authorization form if the submitter agrees).

Thanks again – Tom

---

**From:** Berger, Tom C.  
**Sent:** Wednesday, April 8, 2020 11:06 AM  
**To:** Bauer, Jeff <Bauer.Jeff@epa.gov>; Schweer, Greg <Schweer.Greg@epa.gov>  
**Cc:** Daniels, Rhys G. <daniels@khlaw.com>; Price, Amanda <price@khlaw.com>  
**Subject:** RE: **Ex. 4 CBI**

Jeff – thanks much for the update. Hope you and all at EPA are staying safe.

Tom

---

**From:** Bauer, Jeff <Bauer.Jeff@epa.gov>  
**Sent:** Wednesday, April 8, 2020 11:03 AM  
**To:** Berger, Tom C. <Berger@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>  
**Cc:** Daniels, Rhys G. <daniels@khlaw.com>; Price, Amanda <price@khlaw.com>  
**Subject:** RE: **Ex. 4 CBI**

Tom,

# Ex. 4 CBI

I will follow up with you next wed with a status update.

Jeff Bauer - Program Manager  
United States Environmental Protection Agency (USEPA)  
Office of Pollution Prevention and Toxics (OPPT)  
New Chemicals Program (7405M)  
<http://www.epa.gov/oppt/newchems/>

EPA East Building, room 4133M  
1201 Constitution Ave., NW  
Washington, DC 20004



---

**From:** Berger, Tom C. <Berger@khlaw.com>  
**Sent:** Wednesday, April 08, 2020 10:48 AM  
**To:** Schweer, Greg <Schweer.Greg@epa.gov>  
**Cc:** Daniels, Rhys G. <daniels@khlaw.com>; Bauer, Jeff <Bauer.Jeff@epa.gov>; Price, Amanda <price@khlaw.com>  
**Subject:** RE: **Ex. 4 CBI**

Hi Greg –

I was just going through my to-do list and thought I would circle back on these two cases. I hope everyone is hanging in there.

Thanks again – Tom

---

**From:** Berger, Tom C.  
**Sent:** Monday, March 30, 2020 3:46 PM  
**To:** Schweer, Greg <Schweer.Greg@epa.gov>  
**Cc:** Daniels, Rhys G. <daniels@khlaw.com>; Bauer, Jeff <Bauer.Jeff@epa.gov>; Price, Amanda <price@khlaw.com>  
**Subject:** RE: **Ex. 4 CBI**

Greg / all – completely understood – thank you so much.

Tom

---

**From:** Schweer, Greg <Schweer.Greg@epa.gov>  
**Sent:** Monday, March 30, 2020 3:42 PM  
**To:** Berger, Tom C. <Berger@khlaw.com>  
**Cc:** Daniels, Rhys G. <daniels@khlaw.com>; Bauer, Jeff <Bauer.Jeff@epa.gov>  
**Subject:** RE: **Ex. 4 CBI**

Hi Tom.

I am not ignoring you. I did check with Jeff Bauer early last week on this case. He filled me in on the requests he had made of RAD to review submitted test data and your request for a meeting. However, believe it or not, we have been having issues reliably being able to access our CBI-secure LAN. This hampers our ability to efficiently complete work. I will check on the status of your case as soon as I can.

---

**From:** Berger, Tom C. <Berger@khlaw.com>  
**Sent:** Monday, March 30, 2020 11:51 AM  
**To:** Schweer, Greg <Schweer.Greg@epa.gov>  
**Cc:** Daniels, Rhys G. <daniels@khlaw.com>  
**Subject:** RE: **Ex. 4 CBI**

Hi Greg –

Hope all is well.

Just thought I would check in with you on the **Ex. 4 CBI** LVEA (Lauren Davis) and **Ex. 4 CBI** **Ex. 4 CBI** with Jeff Bauer.

Thanks all always - Tom

---

**From:** Berger, Tom C.  
**Sent:** Tuesday, March 24, 2020 11:12 AM  
**To:** Schweer, Greg <Schweer.Greg@epa.gov>  
**Cc:** Daniels, Rhys G. <daniels@khlaw.com>  
**Subject:** RE: **Ex. 4 CBI**

Greg – thanks so much as always. I also have an LVE with Lauren Davis **Ex. 4 CBI** held up in the process. Lauren has been responsive but the case has stalled (again, however, I understand the challenges you are facing).

These are my two “priority” cases.

Tom

---

**From:** Schweer, Greg <Schweer.Greg@epa.gov>  
**Sent:** Tuesday, March 24, 2020 11:07 AM  
**To:** Berger, Tom C. <Berger@khlaw.com>  
**Cc:** Daniels, Rhys G. <daniels@khlaw.com>  
**Subject:** Re: **Ex. 4 CBI**

Tom,

Yes, things are a bit crazy. I will check into the case status today or tomorrow.

Sent from my iPhone

On Mar 24, 2020, at 10:48 AM, Berger, Tom C. <Berger@khlaw.com> wrote:

Hi Greg –

Obviously things are crazy and I don't want to push Jeff too hard but no response from Jeff on this case for a month.

Hang in there....

Tom

---

**From:** Berger, Tom C.  
**Sent:** Monday, March 23, 2020 6:22 PM  
**To:** Bauer, Jeff <Bauer.Jeff@epa.gov>  
**Cc:** Daniels, Rhys G. <daniels@khlaw.com>  
**Subject:** RE: **Ex. 4 CBI**

Hi Jeff –

Apologies – just want to make sure you are getting these emails. Understand if there are delays.

Tom

---

**From:** Berger, Tom C.  
**Sent:** Thursday, March 19, 2020 5:22 PM  
**To:** Bauer, Jeff <Bauer.Jeff@epa.gov>  
**Cc:** Daniels, Rhys G. <daniels@khlaw.com>  
**Subject:** RE: **Ex. 4 CBI**

Hi Jeff – checking in again – thanks - Tom

---

**From:** Berger, Tom C.  
**Sent:** Monday, March 16, 2020 1:40 PM  
**To:** Bauer, Jeff <Bauer.Jeff@epa.gov>  
**Cc:** Daniels, Rhys G. <daniels@khlaw.com>  
**Subject:** RE: **Ex. 4 CBI**

Hi Jeff –

I know things are crazy but checking in again – thanks - Tom

---

**From:** Berger, Tom C.  
**Sent:** Wednesday, March 11, 2020 3:43 PM  
**To:** Bauer, Jeff <Bauer.Jeff@epa.gov>  
**Cc:** Daniels, Rhys G. <daniels@khlaw.com>  
**Subject:** RE: **Ex. 4 CBI**

Hi Jeff –

Checking in again - thanks

---

**From:** Berger, Tom C.  
**Sent:** Friday, March 6, 2020 1:33 PM  
**To:** Bauer, Jeff <Bauer.Jeff@epa.gov>  
**Cc:** Daniels, Rhys G. <daniels@khlaw.com>  
**Subject:** RE: **Ex. 4 CBI**

Hi Jeff –

The submitter is quite anxious – can we touch base next week?

Thanks much - Tom

---

**From:** Berger, Tom C.  
**Sent:** Tuesday, February 25, 2020 9:08 AM  
**To:** Bauer, Jeff <Bauer.Jeff@epa.gov>  
**Cc:** Daniels, Rhys G. <daniels@khlaw.com>  
**Subject:** RE: **Ex. 4 CBI**

Hi Jeff –

Just checking in on this – thanks - Tom

---

**From:** Berger, Tom C.  
**Sent:** Thursday, February 20, 2020 12:18 PM  
**To:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>  
**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>  
**Subject:** RE: **Ex. 4 CBI**

Hi Jeff –

I hope that all is well.

Per our discussions, the submitter has modified the questions to focus on toxicity/risk issues and submitted them via CDX yesterday. Can we start looking at conference call dates the week of March 9?

Thanks and best regards,  
Tom

Thomas C. Berger  
Partner  
tel: 202.434.4285 | fax: 202.434.4646 | [berger@khlaw.com](mailto:berger@khlaw.com)  
1001 G Street, N.W., Suite 500 West | Washington, D.C. 20001

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**From:** Berger, Tom C.  
**Sent:** Wednesday, January 29, 2020 11:41 AM  
**To:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>  
**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>  
**Subject:** RE: **Ex. 4 CBI**

Hi Jeff –

Apologies we keep playing phone tag – can we discuss how to convert the below questions into questions that would be acceptable to RAD so we can schedule a call with you and RAD? Your voicemail suggested the below are more legal/regulatory than risk-based questions. We still need the below questions answered – perhaps we tee up the more scientific ones for RAD then have the call to address both types of questions. The submitter is under growing commercial pressure.

Thanks much again - Tom

---

**From:** Berger, Tom C.  
**Sent:** Monday, January 20, 2020 3:50 PM  
**To:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>  
**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>  
**Subject:** RE: **Ex. 4 CBI**

Hi Jeff –

Apologies that we could not connect last week. Let's try to touch base tomorrow (Tuesday) if possible to discuss how to move this forward.

Thanks again – Tom

Thomas C. Berger

Partner

tel: 202.434.4285 | fax: 202.434.4646 | [berger@khlaw.com](mailto:berger@khlaw.com)

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**From:** Berger, Tom C.

**Sent:** Monday, January 13, 2020 2:50 PM

**To:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>

**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>

**Subject:** RE: **Ex. 4 CBI**

**Importance:** High

Hi Jeff –

Following is the list of questions we are considering submitting through CDX. Please let me know if these look ok.

Thanks again and best regards,

Tom

\* \* \*

*(1) Based on review of the submitted physical-chemical properties test data, does EPA now agree that use **Ex. 4 CBI** as described in the PMN poses no unreasonable risk of injury and so plans to revoke the consent order?*

*(2) If so, what is the process for revoking the current consent order? Does the submitter now need to request that EPA revoke the order, or will EPA itself initiate revocation? What is the expected timing for revocation? How would EPA communicate such revocation?*

*(3) How would revocation of the consent order impact the final SNUR for the subject substance?*

*(4) Would a SNUN be a more expedient approach?*

\* \* \*

---

**From:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>  
**Sent:** Wednesday, January 8, 2020 8:56 AM  
**To:** Berger, Tom C. <[Berger@khlaw.com](mailto:Berger@khlaw.com)>  
**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>  
**Subject:** RE: **Ex. 4 CBI**

Tom, I am expecting information from the engineer today or tomorrow on the **Ex. 4 CBI** test, I left you a message. There is a new procedure for us to set up meeting with RAD. I am to have the submitter send in a list of questions for RAD, they will assign someone up there as a Lead person who has two weeks and will set a date for when we can have a meeting. This may be our best route to other than just me bugging them to get things done. There were a series of emails on this case last week but now everyone is back from the holidays I am trying to get this case moving again.

Jeff Bauer - Program Manager  
United States Environmental Protection Agency (USEPA)  
Office of Pollution Prevention and Toxics (OPPT)  
New Chemicals Program (7405M)  
<http://www.epa.gov/oppt/newchems/>

EPA East Building, room 4133M  
1201 Constitution Ave., NW  
Washington, DC 20004  
Phone: 202-564-9042, Fax: 202-564-9490

---

**From:** Berger, Tom C. <[Berger@khlaw.com](mailto:Berger@khlaw.com)>  
**Sent:** Tuesday, January 07, 2020 4:16 PM  
**To:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>  
**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>  
**Subject:** RE: **Ex. 4 CBI**

Hi Jeff –

I hope you had a great holiday! The client was wondering if we could have a conference call on this, this week or next. Please advise.

Thanks much – Tom

Thomas C. Berger  
Partner  
tel: 202.434.4285 | fax: 202.434.4646 | [berger@khlaw.com](mailto:berger@khlaw.com)  
1001 G Street, N.W., Suite 500 West | Washington, D.C. 20001

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**From:** Berger, Tom C.  
**Sent:** Tuesday, December 10, 2019 2:10 PM  
**To:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>  
**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>  
**Subject:** RE: **Ex. 4 CBI**

Hi Jeff –

Just checking back in – thanks - Tom

---

**From:** Berger, Tom C.  
**Sent:** Thursday, December 5, 2019 9:46 AM  
**To:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>  
**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>  
**Subject:** RE: **Ex. 4 CBI**

Hi Jeff –

When we spoke before Thanksgiving (I hope you had a great one!) you indicated that the reports were being reviewed and that I should reach out to you in early December.

Is there any update?

Thanks much and best regards – Tom

Thomas C. Berger  
Partner  
tel: 202.434.4285 | fax: 202.434.4646 | [berger@khlaw.com](mailto:berger@khlaw.com)  
1001 G Street, N.W., Suite 500 West | Washington, D.C. 20001

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---

**From:** Berger, Tom C.  
**Sent:** Monday, November 18, 2019 1:17 PM  
**To:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>  
**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>  
**Subject:** RE: **Ex. 4 CBI**

Hi Jeff –

The PMN submitter asked me to reach out to you to see if we can schedule a conference call (including EPA, K&H, and the submitter) on this case re status and pathforward.

Thanks - Tom

---

**From:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>  
**Sent:** Friday, March 29, 2019 5:43 PM  
**To:** Berger, Tom C. <[Berger@khlaw.com](mailto:Berger@khlaw.com)>; Schweer, Greg <[Schweer.Greg@epa.gov](mailto:Schweer.Greg@epa.gov)>  
**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>  
**Subject:** RE: **Ex. 4 CBI**

Tom,  
I set the meeting up for Wednesday April 3, at 11 am. RAD has accepted the invitation for that time.

Jeff Bauer - Program Manager  
United States Environmental Protection Agency (USEPA)  
Office of Pollution Prevention and Toxics (OPPT)  
New Chemicals Program (7405M)  
<http://www.epa.gov/oppt/newchems/>

EPA East Building, room 4133M  
1201 Constitution Ave., NW  
Washington, DC 20004  
Phone: 202-564-9042, Fax: 202-564-9490

---

**From:** Bauer, Jeff  
**Sent:** Tuesday, March 26, 2019 11:37 AM  
**To:** 'Berger, Tom C.' <[Berger@khlaw.com](mailto:Berger@khlaw.com)>; Schweer, Greg <[Schweer.Greg@epa.gov](mailto:Schweer.Greg@epa.gov)>  
**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>  
**Subject:** RE: **Ex. 4 CBI**

Tom, I left you a voice message, I am seeing what time it best for RAD to be part of the call.

Jeff Bauer - Program Manager  
United States Environmental Protection Agency (USEPA)  
Office of Pollution Prevention and Toxics (OPPT)  
New Chemicals Program (7405M)  
<http://www.epa.gov/oppt/newchems/>

EPA East Building, room 4133M  
1201 Constitution Ave., NW  
Washington, DC 20004  
Phone: 202-564-9042, Fax: 202-564-9490

---

**From:** Berger, Tom C. <[Berger@khlaw.com](mailto:Berger@khlaw.com)>  
**Sent:** Tuesday, March 26, 2019 11:30 AM  
**To:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>; Schweer, Greg <[Schweer.Greg@epa.gov](mailto:Schweer.Greg@epa.gov)>  
**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>  
**Subject:** RE: **Ex. 4 CBI**



Hi folks –

Just thought I would check in with you on this.

Thanks again - Tom

---

**From:** Berger, Tom C.

**Sent:** Friday, March 22, 2019 2:12 PM

**To:** 'Bauer.jeff@Epa.gov' <Bauer.jeff@Epa.gov>; 'Schweer, Greg' <Schweer.Greg@epa.gov>

**Cc:** Daniels, Rhys G. <daniels@khlaw.com>

**Subject:** **Ex. 4 CBI**

Hi folks –

I hope you are doing well. Jeff – this is the PMN case that my colleague, Dr. Rhys Daniels, spoke with you about earlier this week.

The issue is development of data needed to amend the existing section 5(e) order for this substance to add an additional use, and EPA approval of protocols for same. Would the Agency be available for a short conference call on this on one of the following days?:

- March 27 (except 12-2 ET)
- April 2
- April 3
- April 4

This is becoming more urgent from a commercial standpoint.

Thanks much - Tom

Thomas C. Berger

Partner

tel: 202.434.4285 | fax: 202.434.4646 | [berger@khlaw.com](mailto:berger@khlaw.com)

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Message

---

**From:** Bob Crouch [bob.crouch@angstrommaterials.com]  
**Sent:** 4/14/2020 9:22:56 PM  
**To:** Schweer, Greg [Schweer.Greg@epa.gov]  
**CC:** Yang, Chun-Chieh [Yang.Chun-Chieh@epa.gov]; Scott J. Burya, Ph.D. [sburya@lawbc.com]; Nathan Holliday [nathan.holliday@g3-am.com]; David Neff [david.neff@g3-am.com]  
**Subject:** FW: Agreement to authorize transmittal of TSCA CBI via Outlook email with designated Agency representatives during the modified working conditions due to COVID-19  
**Attachments:** 00299379.pdf

Dear Mr. Schweer –

Please find attached our authorization for you/EPA to email to us whatever documents are necessary for us to complete the LVE process on the **Ex. 5 Deliberative Process (DP)**

Thank you,  
Bob Crouch  
VP, Legal Affairs  
Global Graphene Group, Inc.

---

**From:** Scott J. Burya, Ph.D. <sburya@lawbc.com>  
**Sent:** Friday, April 10, 2020 11:29 AM  
**To:** 'Bob Crouch' <bob.crouch@angstrommaterials.com>  
**Cc:** Lynn L. Bergeson <lbergeson@lawbc.com>; Richard E. Engler, Ph.D. <rengler@lawbc.com>  
**Subject:** FW: Agreement to authorize transmittal of TSCA CBI via Outlook email with designated Agency representatives during the modified working conditions due to COVID-19

Bob:

Dr. Yang today confirmed that EPA's reports for the **Ex. 5 Deliberative Process (DP)** case were never mailed due to the COVID-19 health emergency.

Please see the e-mail below regarding possible transmittal of EPA's reports via e-mail and the draft Authorization Form appended (document number 299379). Bergeson & Campbell, P.C. (B&C®) has reviewed the language in the Authorization Form and negotiated with EPA to add additional protection for G3's CBI. With the additional language, it is B&C's view that the risk of disclosure of G3's confidential business information is limited to the routine risk of e-mail transmission.

If G3 agrees to allow EPA to use e-mail, please review and sign the appended form and either return to me via e-mail or forward directly to Greg Schweer, with Dr. Yang and me on copy.

Thank you,

**SCOTT J. BURYA, PH.D.**  
**REGULATORY CHEMIST**  
**BERGESON & CAMPBELL PC**  
2200 Pennsylvania Avenue, NW, Suite 100W | Washington, D.C. 20037  
T: 202-266-5013 | F: 202-557-3836 | lawbc.com

---

**From:** Yang, Chun-Chieh <Yang.Chun-Chieh@epa.gov>  
**Sent:** Thursday, April 9, 2020 3:27 PM  
**To:** Scott J. Burya, Ph.D. <sburya@lawbc.com>  
**Cc:** Schweer, Greg <Schweer.Greg@epa.gov>  
**Subject:** Agreement to authorize transmittal of TSCA CBI via Outlook email with designated Agency representatives during the modified working conditions due to COVID-19

Dear Dr. Burya:

In an effort to encourage social distancing and help reduce community spread of COVID-19, most EPA staff have been authorized to telework until at least April 30, 2020. With a majority of EPA staff now teleworking from remote sites, some minor changes to the normal TSCA section 5 review processes, including the TSCA section 5(a)(3) determination processes, are required. Specifically, the normal process by which section 5(a)(3)(C) determination documents and section 5(e) orders are transmitted to submitters, because they contain information claimed as CBI, are hard copies submitted by the mail or courier services and via fax machines. These methods of delivery are not available from remote sites and therefore other means of transmitting this information must be utilized.

Given this extraordinary situation, and to avoid delay in addressing TSCA section 5 requirements, the Agency is offering an option to allowed affected persons to agree to allow EPA to transmit these materials via normal non-encrypted Outlook email. If you agree to this, the Agency will transmit these documents to you via email during the period in which a majority of EPA staff is teleworking. In the absence of this agreement EPA may need to extend the review period for your submission or issue a unilateral order under Section 5(e). Please note that EPA is not requiring companies to agree to transmission via email. Rather this communication explains the constraints we are acting under, and the delays that would result in the absence of email transmission. Companies are free to choose as appropriate.

Also, please note that agreeing to this process is a limited waiver of the TSCA CBI procedural protections, which generally restricts the transmission of CBI over a non-encrypted email system. That said, EPA's email system is compliant with all applicable Federal government information security provisions, including the Federal Information Security Management Act, and EPA's email systems meet the level of protection required for storing and transmitting CBI. Furthermore, your agreement will not constitute a waiver of substantive CBI protections, meaning that the information transmitted and claimed as confidential will only be disclosed consistent with TSCA, other applicable laws, and associated implementing regulations.

If you wish to grant EPA a limited waiver to transmit the materials via EPA's email system during the period in which a majority of EPA staff is teleworking, please have your authorized representative complete, sign, and return the attached to Greg Schweer ([Schweer.greg@epa.gov](mailto:Schweer.greg@epa.gov)) as well as to any EPA staff who were cc'd on the email sent to you. Also please follow the instructions below for the transmittal of information subject to this agreement. If you have any questions about this communication or the described process, please contact Greg Schweer at (202) 564-8469 or the EPA Program Manager assigned to the case.

\*\*\*\*\*

Chun-Chieh Yang  
Biologist / Physical Scientist  
6128H, WJC-East  
NCMB, CCD, OCSPP-OPPT, US EPA  
1201 Constitution Avenue NW  
Washington DC 20460  
Tel: 202-5644821

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**Agreement to authorize transmittal of TSCA Confidential Business Information (CBI) via Outlook email by designated Agency representatives during the period of EPA telework due to COVID-19**

Documents concerning: **Ex. 5 Deliberative Process (DP)**

**COMPANY** authorizes EPA to transmit documents related to the above referenced TSCA submission, including information claimed as CBI, to **COMPANY** through EPA's Outlook email system. **Ex. 5 Deliberative Process (DP)**

**Ex. 5 Deliberative Process (DP)** are teleworking due to COVID-19 concerns and may be withdrawn at any time. Nothing in this authorization diminishes or otherwise limits **COMPANY'S** protections under TSCA to assert information as CBI, or otherwise authorizes the release of any information claimed as CBI without exhausting all provisions of TSCA protecting the release of such information. I have the authority to sign this on behalf of **COMPANY**

Signature of authorized person: /Robert G. Crouch/

Name of authorized person printed or typed: Robert Crouch

Title: Vice President, Legal Affairs

Email address: bob.crouch@angstrommaterials.com

Telephone number: **Ex. 5 Deliberative Process (DP)**

**COMPANY** Global Graphene Group, Inc.

Message

---

**From:** Berger, Tom C. [Berger@khlaw.com]  
**Sent:** 4/14/2020 1:03:16 PM  
**To:** Schweer, Greg [Schweer.Greg@epa.gov]  
**CC:** Daniels, Rhys G. [daniels@khlaw.com]; Price, Amanda [price@khlaw.com]  
**Subject:** RE: **Ex. 4 CBI**

Hi Greg –

Thanks again – I hope all is still well.

As to the other case, the submitter of the **Ex. 4 CBI** LVEA (Case manager = Lauren Davis) has inquired as to status. Do you have an update? I will check with Lauren as well.

Best regards,  
Tom

---

**From:** Berger, Tom C.  
**Sent:** Wednesday, April 8, 2020 11:06 AM  
**To:** Bauer, Jeff <Bauer.Jeff@epa.gov>; Schweer, Greg <Schweer.Greg@epa.gov>  
**Cc:** Daniels, Rhys G. <daniels@khlaw.com>; Price, Amanda <price@khlaw.com>  
**Subject:** RE: **Ex. 4 CBI**

Jeff – thanks much for the update. Hope you and all at EPA are staying safe.

Tom

---

**From:** Bauer, Jeff <Bauer.Jeff@epa.gov>  
**Sent:** Wednesday, April 8, 2020 11:03 AM  
**To:** Berger, Tom C. <Berger@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>  
**Cc:** Daniels, Rhys G. <daniels@khlaw.com>; Price, Amanda <price@khlaw.com>  
**Subject:** RE: **Ex. 4 CBI**

Tom,

# Ex. 4 CBI

I will follow up with you next wed with a status update.

Jeff Bauer - Program Manager  
United States Environmental Protection Agency (USEPA)  
Office of Pollution Prevention and Toxics (OPPT)  
New Chemicals Program (7405M)  
<http://www.epa.gov/oppt/newchems/>

EPA East Building, room 4133M  
1201 Constitution Ave., NW

Washington, DC 20004  
Phone: 202-564-9042, Fax: 202-564-9490

---

**From:** Berger, Tom C. <Berger@khlaw.com>  
**Sent:** Wednesday, April 08, 2020 10:48 AM  
**To:** Schweer, Greg <Schweer.Greg@epa.gov>  
**Cc:** Daniels, Rhys G. <daniels@khlaw.com>; Bauer, Jeff <Bauer.Jeff@epa.gov>; Price, Amanda <price@khlaw.com>  
**Subject:** RE: **Ex. 4 CBI**

Hi Greg –

I was just going through my to-do list and thought I would circle back on these two cases. I hope everyone is hanging in there.

Thanks again – Tom

---

**From:** Berger, Tom C.  
**Sent:** Monday, March 30, 2020 3:46 PM  
**To:** Schweer, Greg <Schweer.Greg@epa.gov>  
**Cc:** Daniels, Rhys G. <daniels@khlaw.com>; Bauer, Jeff <Bauer.Jeff@epa.gov>; Price, Amanda <price@khlaw.com>  
**Subject:** RE: **Ex. 4 CBI**

Greg / all – completely understood – thank you so much.

Tom

---

**From:** Schweer, Greg <Schweer.Greg@epa.gov>  
**Sent:** Monday, March 30, 2020 3:42 PM  
**To:** Berger, Tom C. <Berger@khlaw.com>  
**Cc:** Daniels, Rhys G. <daniels@khlaw.com>; Bauer, Jeff <Bauer.Jeff@epa.gov>  
**Subject:** RE: **Ex. 4 CBI**

Hi Tom.

I am not ignoring you. I did check with Jeff Bauer early last week on this case. He filled me in on the requests he had made of RAD to review submitted test data and your request for a meeting. However, believe it or not, we have been having issues reliably being able to access our CBI-secure LAN. This hampers our ability to efficiently complete work. I will check on the status of your case as soon as I can.

---

**From:** Berger, Tom C. <Berger@khlaw.com>  
**Sent:** Monday, March 30, 2020 11:51 AM  
**To:** Schweer, Greg <Schweer.Greg@epa.gov>  
**Cc:** Daniels, Rhys G. <daniels@khlaw.com>  
**Subject:** RE: **Ex. 4 CBI**

Hi Greg –

Hope all is well.

Just thought I would check in with you on the **Ex. 4 CBI** LVEA (Lauren Davis) and **Ex. 4 CBI** **Ex. 4 CBI** with Jeff Bauer.

Thanks all always - Tom

---

**From:** Berger, Tom C.  
**Sent:** Tuesday, March 24, 2020 11:12 AM  
**To:** Schweer, Greg <Schweer.Greg@epa.gov>  
**Cc:** Daniels, Rhys G. <daniels@khlaw.com>  
**Subject:** RE: Ex. 4 CBI

Greg – thanks so much as always. I also have an LVE with Lauren Davis Ex. 4 CBI held up in the process. Lauren has been responsive but the case has stalled (again, however, I understand the challenges you are facing).

These are my two “priority” cases.

Tom

---

**From:** Schweer, Greg <Schweer.Greg@epa.gov>  
**Sent:** Tuesday, March 24, 2020 11:07 AM  
**To:** Berger, Tom C. <Berger@khlaw.com>  
**Cc:** Daniels, Rhys G. <daniels@khlaw.com>  
**Subject:** Re: Ex. 4 CBI

Tom,

Yes, things are a bit crazy. I will check into the case status today or tomorrow.

Sent from my iPhone

On Mar 24, 2020, at 10:48 AM, Berger, Tom C. <Berger@khlaw.com> wrote:

Hi Greg –

Obviously things are crazy and I don't want to push Jeff too hard but no response from Jeff on this case for a month.

Hang in there....

Tom

---

**From:** Berger, Tom C.  
**Sent:** Monday, March 23, 2020 6:22 PM  
**To:** Bauer, Jeff <Bauer.Jeff@epa.gov>  
**Cc:** Daniels, Rhys G. <daniels@khlaw.com>  
**Subject:** RE: Ex. 4 CBI

Hi Jeff –

Apologies – just want to make sure you are getting these emails. Understand if there are delays.

Tom



---

**From:** Berger, Tom C.  
**Sent:** Thursday, March 19, 2020 5:22 PM  
**To:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>  
**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>  
**Subject:** RE: **Ex. 4 CBI**

Hi Jeff – checking in again – thanks - Tom

---

**From:** Berger, Tom C.  
**Sent:** Monday, March 16, 2020 1:40 PM  
**To:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>  
**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>  
**Subject:** RE: **Ex. 4 CBI**

Hi Jeff –

I know things are crazy but checking in again – thanks - Tom

---

**From:** Berger, Tom C.  
**Sent:** Wednesday, March 11, 2020 3:43 PM  
**To:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>  
**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>  
**Subject:** RE: **Ex. 4 CBI**

Hi Jeff –

Checking in again - thanks

---

**From:** Berger, Tom C.  
**Sent:** Friday, March 6, 2020 1:33 PM  
**To:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>  
**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>  
**Subject:** RE: **Ex. 4 CBI**

Hi Jeff –

The submitter is quite anxious – can we touch base next week?

Thanks much - Tom

---

**From:** Berger, Tom C.  
**Sent:** Tuesday, February 25, 2020 9:08 AM  
**To:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>  
**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>  
**Subject:** RE: **Ex. 4 CBI**

Hi Jeff –

Just checking in on this – thanks - Tom

---

**From:** Berger, Tom C.  
**Sent:** Thursday, February 20, 2020 12:18 PM  
**To:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>  
**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>  
**Subject:** RE: **Ex. 4 CBI**

Hi Jeff –

I hope that all is well.

Per our discussions, the submitter has modified the questions to focus on toxicity/risk issues and submitted them via CDX yesterday. Can we start looking at conference call dates the week of March 9?

Thanks and best regards,  
Tom

Thomas C. Berger  
Partner  
tel: 202.434.4285 | fax: 202.434.4646 | [berger@khlaw.com](mailto:berger@khlaw.com)  
1001 G Street, N.W., Suite 500 West | Washington, D.C. 20001

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**From:** Berger, Tom C.  
**Sent:** Wednesday, January 29, 2020 11:41 AM  
**To:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>  
**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>  
**Subject:** RE: **Ex. 4 CBI**

Hi Jeff –

Apologies we keep playing phone tag – can we discuss how to convert the below questions into questions that would be acceptable to RAD so we can schedule a call with you and RAD? Your voicemail suggested the below are more legal/regulatory than risk-based questions. We still need the below questions answered – perhaps we tee up the more scientific ones for RAD then have the call to address both types of questions. The submitter is under growing commercial pressure.

Thanks much again - Tom

---

**From:** Berger, Tom C.  
**Sent:** Monday, January 20, 2020 3:50 PM  
**To:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>  
**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>  
**Subject:** RE: **Ex. 4 CBI**

Hi Jeff –

Apologies that we could not connect last week. Let's try to touch base tomorrow (Tuesday) if possible to discuss how to move this forward.

Thanks again – Tom

Thomas C. Berger

Partner

tel: 202.434.4285 | fax: 202.434.4646 | [berger@khlaw.com](mailto:berger@khlaw.com)

1001 G Street, N.W., Suite 500 West | Washington, D.C. 20001

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**From:** Berger, Tom C.

**Sent:** Monday, January 13, 2020 2:50 PM

**To:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>

**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>

**Subject:** RE: **Ex. 4 CBI**

**Importance:** High

Hi Jeff –

Following is the list of questions we are considering submitting through CDX. Please let me know if these look ok.

Thanks again and best regards,

Tom

\* \* \*

*(1) Based on review of the submitted physical-chemical properties test data, does EPA now agree that use of **Ex. 4 CBI** as described in the PMN poses no unreasonable risk of injury and so plans to revoke the consent order?*

*(2) If so, what is the process for revoking the current consent order? Does the submitter now need to request that EPA revoke the order, or will EPA itself initiate revocation? What is the expected timing for revocation? How would EPA communicate such revocation?*

*(3) How would revocation of the consent order impact the final SNUR for the subject substance?*

*(4) Would a SNUN be a more expedient approach?*

\* \* \*

---

**From:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>  
**Sent:** Wednesday, January 8, 2020 8:56 AM  
**To:** Berger, Tom C. <[Berger@khlaw.com](mailto:Berger@khlaw.com)>  
**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>  
**Subject:** RE: **Ex. 4 CBI**

Tom, I am expecting information from the engineer today or tomorrow on the **Ex. 4 CBI** test, I left you a message. There is a new procedure for us to set up meeting with RAD. I am to have the submitter send in a list of questions for RAD, they will assign someone up there as a Lead person who has two weeks and will set a date for when we can have a meeting. This may be our best route to other than just me bugging them to get things done. There were a series of emails on this case last week but now everyone is back from the holidays I am trying to get this case moving again.

Jeff Bauer - Program Manager  
United States Environmental Protection Agency (USEPA)  
Office of Pollution Prevention and Toxics (OPPT)  
New Chemicals Program (7405M)  
<http://www.epa.gov/oppt/newchems/>

EPA East Building, room 4133M  
1201 Constitution Ave., NW  
Washington, DC 20004  
Phone: 202-564-9042, Fax: 202-564-9490

---

**From:** Berger, Tom C. <[Berger@khlaw.com](mailto:Berger@khlaw.com)>  
**Sent:** Tuesday, January 07, 2020 4:16 PM  
**To:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>  
**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>  
**Subject:** RE: **Ex. 4 CBI**

Hi Jeff –

I hope you had a great holiday! The client was wondering if we could have a conference call on this, this week or next. Please advise.

Thanks much – Tom

Thomas C. Berger  
Partner  
tel: 202.434.4285 | fax: 202.434.4646 | [berger@khlaw.com](mailto:berger@khlaw.com)  
1001 G Street, N.W., Suite 500 West | Washington, D.C. 20001

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**From:** Berger, Tom C.  
**Sent:** Tuesday, December 10, 2019 2:10 PM  
**To:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>  
**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>  
**Subject:** RE: **Ex. 4 CBI**

Hi Jeff –

Just checking back in – thanks - Tom

---

**From:** Berger, Tom C.  
**Sent:** Thursday, December 5, 2019 9:46 AM  
**To:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>  
**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>  
**Subject:** RE: **Ex. 4 CBI**

Hi Jeff –

When we spoke before Thanksgiving (I hope you had a great one!) you indicated that the reports were being reviewed and that I should reach out to you in early December.

Is there any update?

Thanks much and best regards – Tom

Thomas C. Berger  
Partner  
tel: 202.434.4285 | fax: 202.434.4646 | [berger@khlaw.com](mailto:berger@khlaw.com)  
1001 G Street, N.W., Suite 500 West | Washington, D.C. 20001

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**From:** Berger, Tom C.  
**Sent:** Monday, November 18, 2019 1:17 PM  
**To:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>  
**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>  
**Subject:** RE: **Ex. 4 CBI**

Hi Jeff –

The PMN submitter asked me to reach out to you to see if we can schedule a conference call (including EPA, K&H, and the submitter) on this case re status and pathforward.

Thanks - Tom

---

**From:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>  
**Sent:** Friday, March 29, 2019 5:43 PM  
**To:** Berger, Tom C. <[Berger@khlaw.com](mailto:Berger@khlaw.com)>; Schweer, Greg <[Schweer.Greg@epa.gov](mailto:Schweer.Greg@epa.gov)>  
**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>  
**Subject:** RE: **Ex. 4 CBI**

Tom,  
I set the meeting up for Wednesday April 3, at 11 am. RAD has accepted the invitation for that time.

Jeff Bauer - Program Manager  
United States Environmental Protection Agency (USEPA)  
Office of Pollution Prevention and Toxics (OPPT)  
New Chemicals Program (7405M)  
<http://www.epa.gov/oppt/newchems/>

EPA East Building, room 4133M  
1201 Constitution Ave., NW  
Washington, DC 20004  
Phone: 202-564-9042, Fax: 202-564-9490

---

**From:** Bauer, Jeff  
**Sent:** Tuesday, March 26, 2019 11:37 AM  
**To:** 'Berger, Tom C.' <[Berger@khlaw.com](mailto:Berger@khlaw.com)>; Schweer, Greg <[Schweer.Greg@epa.gov](mailto:Schweer.Greg@epa.gov)>  
**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>  
**Subject:** RE: **Ex. 4 CBI**

Tom, I left you a voice message, I am seeing what time it best for RAD to be part of the call.

Jeff Bauer - Program Manager  
United States Environmental Protection Agency (USEPA)  
Office of Pollution Prevention and Toxics (OPPT)  
New Chemicals Program (7405M)  
<http://www.epa.gov/oppt/newchems/>

EPA East Building, room 4133M  
1201 Constitution Ave., NW  
Washington, DC 20004  
Phone: 202-564-9042, Fax: 202-564-9490

---

**From:** Berger, Tom C. <[Berger@khlaw.com](mailto:Berger@khlaw.com)>  
**Sent:** Tuesday, March 26, 2019 11:30 AM  
**To:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>; Schweer, Greg <[Schweer.Greg@epa.gov](mailto:Schweer.Greg@epa.gov)>  
**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>  
**Subject:** RE: **Ex. 4 CBI**

Hi folks –

Just thought I would check in with you on this.

Thanks again - Tom

---

**From:** Berger, Tom C.

**Sent:** Friday, March 22, 2019 2:12 PM

**To:** 'Bauer.jeff@Epa.gov' <[Bauer.jeff@Epa.gov](mailto:Bauer.jeff@Epa.gov)>; 'Schweer, Greg' <[Schweer.Greg@epa.gov](mailto:Schweer.Greg@epa.gov)>

**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>

**Subject:** **Ex. 4 CBI**

Hi folks –

I hope you are doing well. Jeff – this is the PMN case that my colleague, Dr. Rhys Daniels, spoke with you about earlier this week.

The issue is development of data needed to amend the existing section 5(e) order for this substance to add an additional use, and EPA approval of protocols for same. Would the Agency be available for a short conference call on this on one of the following days?:

- March 27 (except 12-2 ET)
- April 2
- April 3
- April 4

This is becoming more urgent from a commercial standpoint.

Thanks much - Tom

Thomas C. Berger

Partner

tel: 202.434.4285 | fax: 202.434.4646 | [berger@khlaw.com](mailto:berger@khlaw.com)

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Message

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**From:** Yang, Chun-Chieh [Yang.Chun-Chieh@epa.gov]  
**Sent:** 4/9/2020 7:27:13 PM  
**To:** Scott J. Burya, Ph.D. [sburya@lawbc.com]  
**CC:** Schweer, Greg [Schweer.Greg@epa.gov]  
**Subject:** Agreement to authorize transmittal of TSCA CBI via Outlook email with designated Agency representatives during the modified working conditions due to COVID-19  
**Attachments:** Authorization Form for CBI transmittal by e-mail revised 4-8.docx

Dear Dr. Burya:

In an effort to encourage social distancing and help reduce community spread of COVID-19, most EPA staff have been authorized to telework until at least April 30, 2020. With a majority of EPA staff now teleworking from remote sites, some minor changes to the normal TSCA section 5 review processes, including the TSCA section 5(a)(3) determination processes, are required. Specifically, the normal process by which section 5(a)(3)(C) determination documents and section 5(e) orders are transmitted to submitters, because they contain information claimed as CBI, are hard copies submitted by the mail or courier services and via fax machines. These methods of delivery are not available from remote sites and therefore other means of transmitting this information must be utilized.

Given this extraordinary situation, and to avoid delay in addressing TSCA section 5 requirements, the Agency is offering an option to allowed affected persons to agree to allow EPA to transmit these materials via normal non-encrypted Outlook email. If you agree to this, the Agency will transmit these documents to you via email during the period in which a majority of EPA staff is teleworking. In the absence of this agreement EPA may need to extend the review period for your submission or issue a unilateral order under Section 5(e). Please note that EPA is not requiring companies to agree to transmission via email. Rather this communication explains the constraints we are acting under, and the delays that would result in the absence of email transmission. Companies are free to choose as appropriate.

Also, please note that agreeing to this process is a limited waiver of the TSCA CBI procedural protections, which generally restricts the transmission of CBI over a non-encrypted email system. That said, EPA's email system is compliant with all applicable Federal government information security provisions, including the Federal Information Security Management Act, and EPA's email systems meet the level of protection required for storing and transmitting CBI. Furthermore, your agreement will not constitute a waiver of substantive CBI protections, meaning that the information transmitted and claimed as confidential will only be disclosed consistent with TSCA, other applicable laws, and associated implementing regulations.

If you wish to grant EPA a limited waiver to transmit the materials via EPA's email system during the period in which a majority of EPA staff is teleworking, please have your authorized representative complete, sign, and return the attached to Greg Schweer (Schweer.greg@epa.gov) as well as to any EPA staff who were cc'd on the email sent to you. Also please follow the instructions below for the transmittal of information subject to this agreement. If you have any questions about this communication or the described process, please contact Greg Schweer at (202) 564-8469 or the EPA Program Manager assigned to the case.

\*\*\*\*\*

Chun-Chieh Yang  
Biologist / Physical Scientist  
6128H, WJC-East  
NCMB, CCD, OCSPP-OPPT, US EPA



1201 Constitution Avenue NW  
Washington DC 20460  
Tel: 202-5644821

**Agreement to authorize transmittal of TSCA Confidential Business Information (CBI) via Outlook email by designated Agency representatives during the period of EPA telework due to COVID-19**

Documents concerning: PMN-XX-XXX

**COMPANY** authorizes EPA to transmit documents related to the above referenced TSCA submission, including information claimed as CBI, to **COMPANY** through EPA's Outlook email system. This authorization applies only during those periods where EPA staff working on PMN-XX-XXX are teleworking due to COVID-19 concerns and may be withdrawn at any time. Nothing in this authorization diminishes or otherwise limits **COMPANY'S** protections under TSCA to assert information as CBI, or otherwise authorizes the release of any information claimed as CBI without exhausting all provisions of TSCA protecting the release of such information. I have the authority to sign this on behalf of **COMPANY**

Signature of authorized person: \_\_\_\_\_

Name of authorized person printed or typed: \_\_\_\_\_

Title: \_\_\_\_\_

Email address: \_\_\_\_\_

Telephone number: \_\_\_\_\_

**COMPANY** \_\_\_\_\_

Message

---

**From:** Berger, Tom C. [Berger@khlaw.com]  
**Sent:** 4/8/2020 3:06:07 PM  
**To:** Bauer, Jeff [Bauer.Jeff@epa.gov]; Schweer, Greg [Schweer.Greg@epa.gov]  
**CC:** Daniels, Rhys G. [daniels@khlaw.com]; Price, Amanda [price@khlaw.com]  
**Subject:** RE: P-16-05X3

Jeff – thanks much for the update. Hope you and all at EPA are staying safe.

Tom

---

**From:** Bauer, Jeff <Bauer.Jeff@epa.gov>  
**Sent:** Wednesday, April 8, 2020 11:03 AM  
**To:** Berger, Tom C. <Berger@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>  
**Cc:** Daniels, Rhys G. <daniels@khlaw.com>; Price, Amanda <price@khlaw.com>  
**Subject:** RE: P-16-05X3

Tom,

I am having a engineering report run with inhalation exposure so that the HH assessor and I are working of the same exposure for worker inhalation exposure and fugitive air releases. Ex. 5 Attorney Client (AC) I

## Ex. 5 Attorney Client (AC)

I will follow up with you next wed with a status update.

Jeff Bauer - Program Manager  
United States Environmental Protection Agency (USEPA)  
Office of Pollution Prevention and Toxics (OPPT)  
New Chemicals Program (7405M)  
<http://www.epa.gov/oppt/newchems/>

EPA East Building, room 4133M  
1201 Constitution Ave., NW  
Washington, DC 20004  
Phone: 202-564-9042, Fax: 202-564-9490

---

**From:** Berger, Tom C. <Berger@khlaw.com>  
**Sent:** Wednesday, April 08, 2020 10:48 AM  
**To:** Schweer, Greg <Schweer.Greg@epa.gov>  
**Cc:** Daniels, Rhys G. <daniels@khlaw.com>; Bauer, Jeff <Bauer.Jeff@epa.gov>; Price, Amanda <price@khlaw.com>  
**Subject:** RE: P-16-05X3

Hi Greg –

I was just going through my to-do list and thought I would circle back on these two cases. I hope everyone is hanging in there.

Thanks again – Tom

---

**From:** Berger, Tom C.

**Sent:** Monday, March 30, 2020 3:46 PM

**To:** Schweer, Greg <[Schweer.Greg@epa.gov](mailto:Schweer.Greg@epa.gov)>

**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>; Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>; Price, Amanda <[price@khlaw.com](mailto:price@khlaw.com)>

**Subject:** RE: P-16-05X3

Greg / all – completely understood – thank you so much.

Tom

---

**From:** Schweer, Greg <[Schweer.Greg@epa.gov](mailto:Schweer.Greg@epa.gov)>

**Sent:** Monday, March 30, 2020 3:42 PM

**To:** Berger, Tom C. <[Berger@khlaw.com](mailto:Berger@khlaw.com)>

**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>; Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>

**Subject:** RE: P-16-05X3

Hi Tom.

I am not ignoring you. I did check with Jeff Bauer early last week on this case. He filled me in on the requests he had made of RAD to review submitted test data and your request for a meeting. However, believe it or not, we have been having issues reliably being able to access our CBI-secure LAN. This hampers our ability to efficiently complete work. I will check on the status of your case as soon as I can.

---

**From:** Berger, Tom C. <[Berger@khlaw.com](mailto:Berger@khlaw.com)>

**Sent:** Monday, March 30, 2020 11:51 AM

**To:** Schweer, Greg <[Schweer.Greg@epa.gov](mailto:Schweer.Greg@epa.gov)>

**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>

**Subject:** RE: P-16-05X3

Hi Greg –

Hope all is well.

Just thought I would check in with you on the Green Chemistry award winner LVEA (Lauren Davis) and P-16-05X3 (where I had hidden the integer “X”) with Jeff Bauer.

Thanks all always - Tom

---

**From:** Berger, Tom C.

**Sent:** Tuesday, March 24, 2020 11:12 AM

**To:** Schweer, Greg <[Schweer.Greg@epa.gov](mailto:Schweer.Greg@epa.gov)>

**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>

**Subject:** RE: P-16-05X3

Greg – thanks so much as always. I also have an LVE with Lauren Davis where a Green Chemistry award winner is held up in the process. Lauren has been responsive but the case has stalled (again, however, I understand the challenges you are facing).

These are my two “priority” cases.

Tom

---

**From:** Schweer, Greg <[Schweer.Greg@epa.gov](mailto:Schweer.Greg@epa.gov)>  
**Sent:** Tuesday, March 24, 2020 11:07 AM  
**To:** Berger, Tom C. <[Berger@khlaw.com](mailto:Berger@khlaw.com)>  
**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>  
**Subject:** Re: P-16-05X3

Tom,

Yes, things are a bit crazy. I will check into the case status today or tomorrow.

Sent from my iPhone

On Mar 24, 2020, at 10:48 AM, Berger, Tom C. <[Berger@khlaw.com](mailto:Berger@khlaw.com)> wrote:

Hi Greg –

Obviously things are crazy and I don't want to push Jeff too hard but no response from Jeff on this case for a month.

Hang in there....

Tom

---

**From:** Berger, Tom C.  
**Sent:** Monday, March 23, 2020 6:22 PM  
**To:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>  
**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>  
**Subject:** RE: P-16-05X3

Hi Jeff –

Apologies – just want to make sure you are getting these emails. Understand if there are delays.

Tom

---

**From:** Berger, Tom C.  
**Sent:** Thursday, March 19, 2020 5:22 PM  
**To:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>  
**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>  
**Subject:** RE: P-16-05X3

Hi Jeff – checking in again – thanks - Tom

---

**From:** Berger, Tom C.  
**Sent:** Monday, March 16, 2020 1:40 PM  
**To:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>  
**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>  
**Subject:** RE: P-16-05X3

Hi Jeff –

I know things are crazy but checking in again – thanks - Tom

---

**From:** Berger, Tom C.  
**Sent:** Wednesday, March 11, 2020 3:43 PM  
**To:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>  
**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>  
**Subject:** RE: P-16-05X3

Hi Jeff –

Checking in again - thanks

---

**From:** Berger, Tom C.  
**Sent:** Friday, March 6, 2020 1:33 PM  
**To:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>  
**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>  
**Subject:** RE: P-16-05X3

Hi Jeff –

The submitter is quite anxious – can we touch base next week?

Thanks much - Tom

---

**From:** Berger, Tom C.  
**Sent:** Tuesday, February 25, 2020 9:08 AM  
**To:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>  
**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>  
**Subject:** RE: P-16-05X3

Hi Jeff –

Just checking in on this – thanks - Tom

---

**From:** Berger, Tom C.  
**Sent:** Thursday, February 20, 2020 12:18 PM  
**To:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>  
**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>  
**Subject:** RE: P-16-05X3

Hi Jeff –

I hope that all is well.

Per our discussions, the submitter has modified the questions to focus on toxicity/risk issues and submitted them via CDX yesterday. Can we start looking at conference call dates the week of March 9?

Thanks and best regards,  
Tom

Thomas C. Berger  
Partner  
tel: 202.434.4285 | fax: 202.434.4646 | [berger@khlaw.com](mailto:berger@khlaw.com)  
1001 G Street, N.W., Suite 500 West | Washington, D.C. 20001

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---

**From:** Berger, Tom C.  
**Sent:** Wednesday, January 29, 2020 11:41 AM  
**To:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>  
**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>  
**Subject:** RE: P-16-05X3

Hi Jeff –

Apologies we keep playing phone tag – can we discuss how to convert the below questions into questions that would be acceptable to RAD so we can schedule a call with you and RAD? Your voicemail

S  
C  
H

## Ex. 5 Attorney Client (AC)

Thanks much again - Tom

---

**From:** Berger, Tom C.  
**Sent:** Monday, January 20, 2020 3:50 PM  
**To:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>  
**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>  
**Subject:** RE: P-16-05X3

Hi Jeff –

Apologies that we could not connect last week. Let's try to touch base tomorrow (Tuesday) if possible to discuss how to move this forward.

Thanks again – Tom

Thomas C. Berger  
Partner  
tel: 202.434.4285 | fax: 202.434.4646 | [berger@khlaw.com](mailto:berger@khlaw.com)  
1001 G Street, N.W., Suite 500 West | Washington, D.C. 20001

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---

**From:** Berger, Tom C.  
**Sent:** Monday, January 13, 2020 2:50 PM  
**To:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>  
**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>  
**Subject:** RE: P-16-05X3  
**Importance:** High

Hi Jeff –

Following is the list of questions we are considering submitting through CDX. Please let me know if these look ok.

Thanks again and best regards,  
Tom

\* \* \*

*(1) Based on review of the submitted physical-chemical properties test data, does EPA now agree that use in spray applications as described in the PMN poses no unreasonable risk of injury and so plans to revoke the consent order?*

*(2) If so, what is the process for revoking the current consent order? Does the submitter now need to request that EPA revoke the order, or will EPA itself initiate revocation? What is the expected timing for revocation? How would EPA communicate such revocation?*

*(3) How would revocation of the consent order impact the final SNUR for the subject substance?*

*(4) Would a SNUN be a more expedient approach?*

\* \* \*

---

**From:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>  
**Sent:** Wednesday, January 8, 2020 8:56 AM  
**To:** Berger, Tom C. <[Berger@khlaw.com](mailto:Berger@khlaw.com)>  
**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>  
**Subject:** RE: P-16-05X3

Tom, I am expecting information from the engineer today or tomorrow on the spray test, I left you a message. There is a new procedure for us to set up meeting with RAD. I am to have the submitter send in a list of questions for RAD, they will assign someone up there as a Lead person who has two weeks and will set a date for when we can have a meeting. This may be our best route to other than just me



bugging them to get things done. There were a series of emails on this case last week but now everyone is back from the holidays I am trying to get this case moving again.

Jeff Bauer - Program Manager  
United States Environmental Protection Agency (USEPA)  
Office of Pollution Prevention and Toxics (OPPT)  
New Chemicals Program (7405M)  
<http://www.epa.gov/oppt/newchemicals/>

EPA East Building, room 4133M  
1201 Constitution Ave., NW  
Washington, DC 20004  
Phone: 202-564-9042, Fax: 202-564-9490

---

**From:** Berger, Tom C. <[Berger@khlaw.com](mailto:Berger@khlaw.com)>  
**Sent:** Tuesday, January 07, 2020 4:16 PM  
**To:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>  
**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>  
**Subject:** RE: P-16-05X3

Hi Jeff –

I hope you had a great holiday! The client was wondering if we could have a conference call on this, this week or next. Please advise.

Thanks much – Tom

Thomas C. Berger  
Partner  
tel: 202.434.4285 | fax: 202.434.4646 | [berger@khlaw.com](mailto:berger@khlaw.com)  
1001 G Street, N.W., Suite 500 West | Washington, D.C. 20001

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**From:** Berger, Tom C.  
**Sent:** Tuesday, December 10, 2019 2:10 PM  
**To:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>  
**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>  
**Subject:** RE: P-16-05X3

Hi Jeff –

Just checking back in – thanks - Tom

---

**From:** Berger, Tom C.  
**Sent:** Thursday, December 5, 2019 9:46 AM  
**To:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>  
**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>  
**Subject:** RE: P-16-05X3

Hi Jeff –

When we spoke before Thanksgiving (I hope you had a great one!) you indicated that the reports were being reviewed and that I should reach out to you in early December.

Is there any update?

Thanks much and best regards – Tom

Thomas C. Berger  
Partner  
tel: 202.434.4285 | fax: 202.434.4646 | [berger@khlaw.com](mailto:berger@khlaw.com)  
1001 G Street, N.W., Suite 500 West | Washington, D.C. 20001

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**From:** Berger, Tom C.  
**Sent:** Monday, November 18, 2019 1:17 PM  
**To:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>  
**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>  
**Subject:** RE: P-16-05X3

Hi Jeff –

The PMN submitter asked me to reach out to you to see if we can schedule a conference call (including EPA, K&H, and the submitter) on this case re status and pathforward.

Thanks - Tom

---

**From:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>  
**Sent:** Friday, March 29, 2019 5:43 PM  
**To:** Berger, Tom C. <[Berger@khlaw.com](mailto:Berger@khlaw.com)>; Schweer, Greg <[Schweer.Greg@epa.gov](mailto:Schweer.Greg@epa.gov)>  
**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>  
**Subject:** RE: P-16-05X3

Tom,  
I set the meeting up for Wednesday April 3, at 11 am. RAD has accepted the invitation for that time.

Jeff Bauer - Program Manager  
United States Environmental Protection Agency (USEPA)  
Office of Pollution Prevention and Toxics (OPPT)  
New Chemicals Program (7405M)  
<http://www.epa.gov/oppt/newchemicals/>

EPA East Building, room 4133M  
1201 Constitution Ave., NW  
Washington, DC 20004  
Phone: 202-564-9042, Fax: 202-564-9490

---

**From:** Bauer, Jeff  
**Sent:** Tuesday, March 26, 2019 11:37 AM  
**To:** 'Berger, Tom C.' <[Berger@khlaw.com](mailto:Berger@khlaw.com)>; Schweer, Greg <[Schweer.Greg@epa.gov](mailto:Schweer.Greg@epa.gov)>  
**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>  
**Subject:** RE: P-16-05X3

Tom, I left you a voice message, I am seeing what time it best for RAD to be part of the call.

Jeff Bauer - Program Manager  
United States Environmental Protection Agency (USEPA)  
Office of Pollution Prevention and Toxics (OPPT)  
New Chemicals Program (7405M)  
<http://www.epa.gov/oppt/newchemicals/>

EPA East Building, room 4133M  
1201 Constitution Ave., NW  
Washington, DC 20004  
Phone: 202-564-9042, Fax: 202-564-9490

---

**From:** Berger, Tom C. <[Berger@khlaw.com](mailto:Berger@khlaw.com)>  
**Sent:** Tuesday, March 26, 2019 11:30 AM  
**To:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>; Schweer, Greg <[Schweer.Greg@epa.gov](mailto:Schweer.Greg@epa.gov)>  
**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>  
**Subject:** RE: P-16-05X3

Hi folks –

Just thought I would check in with you on this.

Thanks again - Tom

---

**From:** Berger, Tom C.  
**Sent:** Friday, March 22, 2019 2:12 PM  
**To:** 'Bauer.Jeff@Epa.gov' <[Bauer.Jeff@Epa.gov](mailto:Bauer.Jeff@Epa.gov)>; 'Schweer, Greg' <[Schweer.Greg@epa.gov](mailto:Schweer.Greg@epa.gov)>  
**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>  
**Subject:** P-16-05X3

Hi folks –

I hope you are doing well. Jeff – this is the PMN case that my colleague, Dr. Rhys Daniels, spoke with you about earlier this week.

The issue is development of data needed to amend the existing section 5(e) order for this substance to add an additional use, and EPA approval of protocols for same. Would the Agency be available for a short conference call on this on one of the following days?:

- March 27 (except 12-2 ET)
- April 2
- April 3
- April 4

This is becoming more urgent from a commercial standpoint.

Thanks much - Tom

Thomas C. Berger

Partner

tel: 202.434.4285 | fax: 202.434.4646 | [berger@khlaw.com](mailto:berger@khlaw.com)

1001 G Street, N.W., Suite 500 West | Washington, D.C. 20001

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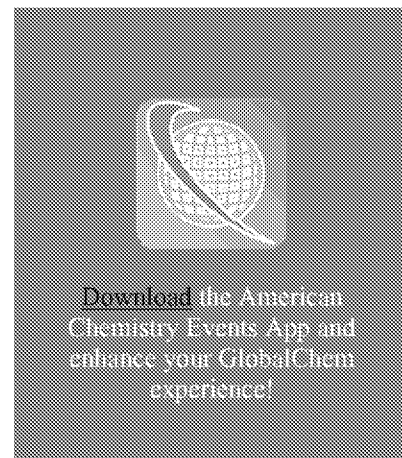
**From:** GlobalChem Conference [online@americanchemistry.com]  
**Sent:** 3/6/2019 1:02:13 PM  
**To:** Schweer, Greg [Schweer.Greg@epa.gov]  
**Subject:** GlobalChem Welcomes You to Washington, DC!



Good morning, and welcome to the Pre-Conference Workshop for the 2019 GlobalChem Conference & Exhibition!

As the business of chemistry's premier policy and regulatory conference, GlobalChem offers a valuable opportunity for industry leaders, regulators and stakeholders to review key developments in the global chemicals management arena. This year, we will explore the lessons stakeholders have learned and strategies for successful implementation of the 2016 amendments to the Toxic Substances Control Act (TSCA).

Before getting into the details of the day ahead, we would like to recognize the principal sponsor of this year's conference, Beveridge & Diamond PC. And, we would like to remind everyone that schedules, session descriptions, speaker information, exhibitor details and hotel information are available on the GlobalChem Conference App, which can be [downloaded here](#) or viewed through your we browser [here](#).



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Today's pre-conference workshop will explore the fundamentals of the amendments to TSCA. All sessions will be in the Palladian Ballroom. Highlights include:

- **PMN Workshop: What to Submit and How to Work with Your PM Manager**  
**9:15 am – 10:30 am**  
TSCA requires EPA to make changes to its new chemicals program. This has changed how EPA and submitters interact, as well as expectations for the process. What are the changes, and how can we address them? This workshop will first outline the changes to the new chemicals program in the TSCA amendments and priorities for EPA's Section 5 program going forward. Second, you will hear from both EPA staff and submitters talk about what hazard and exposure information can support better review and how to work with EPA throughout the submission process.

- Hazard Characterization 101: Basics of Toxicology in TSCA Risk Assessments**  
**1:00 - 2:00 pm**  
 Hazard characterization is the process for determining the types of adverse effects an exposure to a chemical may cause and the conditions under which the adverse effects are induced, such as the route of exposure, magnitude, frequency and duration of exposure and dose response. This session will describe how hazard characterizations are constructed from the principle lines of evidence gathered from epidemiological studies, laboratory toxicity studies, mechanistic studies and in silico computational prediction models. In addition, approaches for integrating lines of evidence to develop weight of evidence conclusions will be presented. As EPA continues its evaluations of the First 10 chemicals for risk evaluation, and prepares to identify 20 potential High Priority candidates for risk evaluation, policy staff and attorneys will need to know how to read and understand scientific language pertaining to hazards. Join us for this brief primer on the basics of toxicology.
- TSCA Fee Basics**  
**4:45 - 5:30 pm**  
 What are the fees for each activity? How will EPA manage the TSCA Fee Program? When should PMN submitters expect refunds? What should EPA be watching for later refinement/improvement for fees assessment and collection as the program matures?

For the full agenda, please visit our website, [www.globalchem.org](http://www.globalchem.org), or [download the Conference App](#).

For real-time news updates from the conference, follow ACC (@AmChemistry) on Twitter and join the conversation by using the hashtag #GlobalChem.

**GlobalChem's Opening Reception and Exhibition Kickoff  
starts at 5:45 pm in the Regency Ballroom!**

*To unsubscribe and stop receiving future emails about the 2019 GlobalChem Conference & Exhibition, click the following link: [http://www.cvent.com/d/ZKM4Ka50YE6oR2\\_LYz7s2A/w7hm/E1/8E?](http://www.cvent.com/d/ZKM4Ka50YE6oR2_LYz7s2A/w7hm/E1/8E?)*

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Message

---

**From:** Franz, Christina [Christina\_Franz@americanchemistry.com]  
**Sent:** 2/27/2019 7:35:26 PM  
**To:** Schweer, Greg [Schweer.Greg@epa.gov]  
**CC:** Pierce, Alison [Pierce.Alison@epa.gov]; Scheifele, Hans [Scheifele.Hans@epa.gov]; Henry, Tala [Henry.Tala@epa.gov]; Wormell, Lance [Wormell.Lance@epa.gov]; Starr, Richard [Richard\_Starr@americanchemistry.com]; Brozena, Sarah [Sarah\_Brozena@americanchemistry.com]; Blanco, Susan [Susan\_Blanco@americanchemistry.com]; Blair, Susanna [Blair.Susanna@epa.gov]  
**Subject:** RE: Names for the PMN Session

Thank you, Greg. I believe so, but will check.

*Christina Franz*

Senior Director, Regulatory & Technical Affairs  
American Chemistry Council  
700 Second St., NE  
Washington, D.C. 20002  
202-249-6406 (o)  
301-580-6562 (c)  
[Christina\\_Franz@americanchemistry.com](mailto:Christina_Franz@americanchemistry.com)

---

**From:** Schweer, Greg [mailto:Schweer.Greg@epa.gov]  
**Sent:** Tuesday, February 26, 2019 8:27 AM  
**To:** Franz, Christina <Christina\_Franz@americanchemistry.com>  
**Cc:** Pierce, Alison <Pierce.Alison@epa.gov>; Scheifele, Hans <Scheifele.Hans@epa.gov>; Henry, Tala <Henry.Tala@epa.gov>; Wormell, Lance <Wormell.Lance@epa.gov>; Starr, Richard <Richard\_Starr@americanchemistry.com>; Brozena, Sarah <Sarah\_Brozena@americanchemistry.com>; Blanco, Susan <Susan\_Blanco@americanchemistry.com>; Blair, Susanna <Blair.Susanna@epa.gov>  
**Subject:** RE: Names for the PMN Session

Christina,

Attached are the bios and pics for three of us (Greg Schweer, Jeff Gallagher, and Scott Prothero). I believe that Rebecca Edelstein already sent her bio and pic to you. I am awaiting bios/pics from Keith Salazar and David Tobias.

Our six presentations are currently being reviewed by the OCSPP IO. Hopefully, that review will be completed soon.

I received a registration confirmation from ACC Meeting Services. I assume that the other five EPA folks for this session will also be registered. Correct assumption?

---

**From:** Schweer, Greg  
**Sent:** Monday, February 25, 2019 4:24 PM  
**To:** 'Franz, Christina' <[Christina\\_Franz@americanchemistry.com](mailto:Christina_Franz@americanchemistry.com)>  
**Cc:** Pierce, Alison <[Pierce.Alison@epa.gov](mailto:Pierce.Alison@epa.gov)>; Scheifele, Hans <[Scheifele.Hans@epa.gov](mailto:Scheifele.Hans@epa.gov)>; Henry, Tala <[Henry.Tala@epa.gov](mailto:Henry.Tala@epa.gov)>; Wormell, Lance <[Wormell.Lance@epa.gov](mailto:Wormell.Lance@epa.gov)>; Starr, Richard <[Richard\\_Starr@americanchemistry.com](mailto:Richard_Starr@americanchemistry.com)>; Brozena, Sarah <[Sarah\\_Brozena@americanchemistry.com](mailto:Sarah_Brozena@americanchemistry.com)>  
**Subject:** RE: Names for the PMN Session

Christina,

Thanks for the followup note. I just put out a request for the remaining bios/pictures from three of the presenters; I already have the other three.

---

**From:** Franz, Christina <[Christina\\_Franz@americanchemistry.com](mailto:Christina_Franz@americanchemistry.com)>  
**Sent:** Monday, February 25, 2019 3:26 PM  
**To:** Schweer, Greg <[Schweer.Greg@epa.gov](mailto:Schweer.Greg@epa.gov)>  
**Cc:** Pierce, Alison <[Pierce.Alison@epa.gov](mailto:Pierce.Alison@epa.gov)>; Scheifele, Hans <[Scheifele.Hans@epa.gov](mailto:Scheifele.Hans@epa.gov)>; Henry, Tala <[Henry.Tala@epa.gov](mailto:Henry.Tala@epa.gov)>; Wormell, Lance <[Wormell.Lance@epa.gov](mailto:Wormell.Lance@epa.gov)>; Starr, Richard <[Richard\\_Starr@americanchemistry.com](mailto:Richard_Starr@americanchemistry.com)>; Brozena, Sarah <[Sarah\\_Brozena@americanchemistry.com](mailto:Sarah_Brozena@americanchemistry.com)>  
**Subject:** RE: Names for the PMN Session

We'll make it work.

Can everyone who has not done so already please send a brief bio and headshot to me as soon as possible?

Thanks very much.

*Christina Franz*

Senior Director, Regulatory & Technical Affairs  
American Chemistry Council  
700 Second St., NE  
Washington, D.C. 20002  
202-249-6406 (o)  
301-580-6562 (c)  
[Christina\\_Franz@americanchemistry.com](mailto:Christina_Franz@americanchemistry.com)

---

**From:** Schweer, Greg [<mailto:Schweer.Greg@epa.gov>]  
**Sent:** Wednesday, February 20, 2019 4:04 PM  
**To:** Franz, Christina <[Christina\\_Franz@americanchemistry.com](mailto:Christina_Franz@americanchemistry.com)>  
**Cc:** Pierce, Alison <[Pierce.Alison@epa.gov](mailto:Pierce.Alison@epa.gov)>; Scheifele, Hans <[Scheifele.Hans@epa.gov](mailto:Scheifele.Hans@epa.gov)>; Henry, Tala <[Henry.Tala@epa.gov](mailto:Henry.Tala@epa.gov)>; Wormell, Lance <[Wormell.Lance@epa.gov](mailto:Wormell.Lance@epa.gov)>; Starr, Richard <[Richard\\_Starr@americanchemistry.com](mailto:Richard_Starr@americanchemistry.com)>; Brozena, Sarah <[Sarah\\_Brozena@americanchemistry.com](mailto:Sarah_Brozena@americanchemistry.com)>  
**Subject:** Re: Names for the PMN Session

Christina,

I am not certain where the communications went astray. I was notified the week we returned from the shutdown that I was responsible for putting together the 2-hour training workshop. No mention was made to me that Kelly was going to be part of the panel. So, we quickly pulled together a team to present what we thought would address the scope of the session. It was not until I rec'd your invitation on Feb 12 for a conference call that I saw Kelly as part of the package. I thought that she perhaps was going to be the Moderator for the session.



Nonetheless, I just spoke with Tala Henry. All of our six presentations have been drafted and are being reviewed by OGC. We think that we can work still use all six EPA presenters but limit their presentations to 12 minutes each, on average, and thus ensure that Kelly has the 25 minutes you have allocated in the proposal below. In the first session, I will lead off, followed by Scott Prothero (worker exposure and environmental release assessment), David Tobias (fate, general population exposure, and consumer exposure), and Jeff Gallagher (eco hazard & risk). Keith Salazar (human health hazard & risk) will lead off the 2nd session, followed by Rebecca Edelstein, and then Kelly.

Sound OK to you?

---

**From:** Franz, Christina <[Christina\\_Franz@americanchemistry.com](mailto:Christina_Franz@americanchemistry.com)>  
**Sent:** Wednesday, February 20, 2019 1:22 PM  
**To:** Schweer, Greg  
**Cc:** Pierce, Alison; Scheifele, Hans; Henry, Tala; Wormell, Lance; Starr, Richard; Brozena, Sarah  
**Subject:** RE: Names for the PMN Session

This was the proposal Kelly and I discussed:

**9:30 AM - 10:30 AM PMN Workshop: Session 1**

Greg Schweer, EPA (25 mins) – TSCA Section 5 Updates, new regulatory determinations, and introduction to the new chemical review process

David Tobias, EPA (25 mins) – Introduction of the Points to Consider Document and outline of additional information to provide with new chemical submissions

Q & A – 10 minutes

**10:45 AM - 11:45 AM PMN Workshop: Session 2**

Rebecca Edelstien, EPA (25 minutes) – PreNotice Communication process and how to coordinate with the Agency post-notification

Kelly Mayo, knoell USA ( 25 minutes) – Tips for preparing notification packages and strategies for supply chain communication

Q & A – 10 minutes

---

**From:** Franz, Christina  
**Sent:** Wednesday, February 20, 2019 12:53 PM  
**To:** Schweer, Greg  
**Cc:** Pierce, Alison; Scheifele, Hans; Henry, Tala; Wormell, Lance; Starr, Richard; Brozena, Sarah  
**Subject:** RE: Names for the PMN Session

Hello Greg:

I am not quite sure what happened in the communications between Richard Starr, Alison Pierce, Hans Scheifele and/or communications between Alison, Hans, and you, but let me try at least to explain my perspective on my own confusion and how I would propose to resolve the confusion.

The panel description that I was given on the Global Chem agenda identifies you and two other EPA presenters--David Tobias and Rebecca Edelstein. The fourth presenter was Kelly Mayo Bean. Kelly's organization is a sponsor, which is expensive and afforded her the opportunity to cover about 40 minutes of the presentation. That is why when I sent out the meeting invite for our discussion a few weeks ago, I sent it to you, David, Rebecca, and Kelly. I was very surprised when we had the call that you had as many people from EPA on the phone and all had a planned presentation. However, I didn't feel I was in a position to say much about it at the moment as a stand-in as moderator because I wasn't certain I had all the facts at my disposal. However, I was surprised by your comment, Greg, during the call that you did not know Kelly was a part of the panel.

Once our call was completed, it became clear the Kelly would not really have much of an opportunity to speak. This is posing a problem for her company as a sponsor. It appears to me, albeit from the outside since I am not part of the organizing team, that a possible miscommunication happened at EPA--largely because Greg said that he did not know Kelly was supposed to be a part of the panel. If I am incorrect about that, my apologies, I am only trying to piece this together. I think the only right thing to do is to return to the original format and divide the presentation up accordingly.

I had a phone conversation with Kelly and made notes on what that division might look like, but I am not in the office this week and do not have it in front of me. I would have to write to her and get that breakout by email. Perhaps it is readily apparent to you knowing her background and those of David and Rebecca, but it is not to me--apologies for that. I do recall that Kelly suggested perhaps the others from EPA you wanted to present could be in attendance to answer questions that the audience might have regarding their areas of expertise.

Does this make sense to folks?

I have copied Richard Starr and Sarah Brozena on this email as well--Richard because he is ACC's Global Chem organizer and Sarah because she was on our panel call with me, although we had agreed that I would moderate the panel.

In closing, it is a shame there has been a mixup with this session. I certainly don't want to offend anyone or cast any aspersions--these things happen sometimes. I just think returning to the original plan is the correct thing to do for all concerned.

Christina

---

**From:** Schweer, Greg [Schweer.Greg@epa.gov]  
**Sent:** Wednesday, February 20, 2019 11:29 AM  
**To:** Franz, Christina  
**Cc:** Pierce, Alison; Scheifele, Hans; Henry, Tala; Wormell, Lance  
**Subject:** Re: Names for the PMN Session

Christina,

This is an interesting turn of events. How do you and Kelly want to schedule her 40 minutes? We will need to shorten our presentations (or at least skip slides) or shorten the Q&A time.

---

**From:** Starr, Richard <Richard\_Starr@americanchemistry.com>  
**Sent:** Wednesday, February 20, 2019 10:55 AM  
**To:** Scheifele, Hans  
**Cc:** Pierce, Alison; Franz, Christina; Schweer, Greg  
**Subject:** Re: Names for the PMN Session

Hi Hans, thanks for the note - I hope you're enjoying the light snow today. This matter is probably better resolved over the phone, but the weather is giving us little choice.

As happens sometimes, I think there may have been a mix up at some point. Kelly is with Knoell consulting, and they have paid for a sponsorship which encompasses a 40 minute presentation, so we will provide her that time, whether it is 20 minutes at the end of each half of the session (which may have been a source of the misunderstanding), or all at once. That is up to the group to split up, of course.

As I mentioned on the phone, the total time is 120 minutes (two one hour sessions with a 15 minute break in between), so the remaining 80 minutes is free to be split up however the group decides.

Sent from my iPhone

On Feb 19, 2019, at 10:06 PM, Scheifele, Hans <[Scheifele.Hans@epa.gov](mailto:Scheifele.Hans@epa.gov)> wrote:

Hi Richard,

I'm following up on our conversation and email last Friday. Sorry for not getting back to you until now. I spoke with Greg Schweer and understand that he, Christina and others, including Kelly I believe, discussed the details last Wednesday and it was agreed that Kelly would have 20 minutes (at the end of the session as I understand it). I need to defer to the decisions of the planning group as discussed and agreed to last week. I've cc'ed Greg here if you have more questions. If I've misunderstood something Greg can clarify and/or discuss details further with Christina and you.

Thanks,  
Hans

On Feb 14, 2019, at 1:36 PM, Starr, Richard <[Richard\\_Starr@americanchemistry.com](mailto:Richard_Starr@americanchemistry.com)> wrote:

Hi Alison (and Hans),

Thank you for providing me with these names.

We truly appreciate the interest in this session, though we'd like to ensure that the format leaves room for the non-EPA presenter on the panel.

I'd like to reduce the number of formal presentations per hour to the original format (unless staff would like to tag in/out). This would ensure that each speaker/presenter could average about 20 minutes per hour including questions (Kelly Mayo's presentation is about 40 minutes, and would thus count for two slots). Any additional folks that do not make formal presentations could certainly be made available for Q&A portions of the session.

I've copied Christina Franz, our moderator for the session, to clarify anything I missed, and help answer any questions about the format we're looking for.

Thank you!

Richard Starr | American Chemistry Council  
Manager, Regulatory & Technical Affairs  
[richard\\_starr@americanchemistry.com](mailto:richard_starr@americanchemistry.com)  
700 2nd Street, NE | Washington, DC | 20002  
O: (202) 249-6443 C: (202) 580-9494  
[www.americanchemistry.com](http://www.americanchemistry.com)

---

**From:** Pierce, Alison [<mailto:Pierce.Alison@epa.gov>]  
**Sent:** Wednesday, February 13, 2019 3:12 PM  
**To:** Starr, Richard  
**Subject:** Names for the PMN Session

Richard – Per discussion, here's our current slew of folks who will be helping out on the PMN session:

- Greg Schweer
- Rebecca Edelstein
- David Tobias
- Jeff Gallagher
- Keith Salazar
- Scott Prothero

Best,  
Alison

**ALISON PIERCE**  
*Office of Pollution Prevention and Toxics  
U.S. Environmental Protection Agency  
1200 Pennsylvania Ave., N.W.  
Washington, DC 20460 USA*

**PIERCE.ALISON@EPA.GOV**  
**202.564.2437**

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Message

---

**From:** Ross, Adam [ross.adam@epa.gov]  
**Sent:** 8/1/2018 4:31:58 PM  
**To:** mike\_walls@americanchemistry.com  
**CC:** Schweer, Greg [Schweer.Greg@epa.gov]; Canavan, Sheila [Canavan.Sheila@epa.gov]; Mullings, Brandon [Mullings.Brandon@epa.gov]  
**Subject:** Request for Assistance on Renewal of Information Collection Request: TSCA Section 5 (EPA ICR No. 0574.18; OMB No. 2070-0012)  
**Attachments:** Consultations Email for Comment 08012018.docx

Dear Mr. Walls:

Enclosed please find a request for comment letter in connection with an EPA Information Collection Request (ICR) for TSCA Section 5. In this letter we explain how to find this ICR and list several questions we hope you might consider during your review. As the letter states we are greatly appreciative of your response to us not later than September 24, 2018.

I am the main point of contact for this ICR and am happy to help you locate documents or answer questions as necessary. Thank you for your attention here.

Adam B. Ross  
Attorney-Advisor  
Chemical Control Division  
Office of Pollution Prevention and Toxics  
US Environmental Protection Agency  
WJC EPA East Building, Room 4419B  
1200 Pennsylvania Avenue, NW  
Washington, DC 20460  
Phone: 202-564-1625  
Fax: 202-564-9490

Date: August 1, 2018

From: Adam Ross/DC/USEPA/US

To: Mike Walls, Vice President  
Regulatory and Technical Affairs  
American Chemistry Council, Inc.  
[ [HYPERLINK "mailto:mike\\_walls@americanchemistry.com"](mailto:mike_walls@americanchemistry.com) ]

Melissa Hockstad, President and CEO  
American Cleaning Institute  
[ [HYPERLINK "mailto:erosenberg@cleaninginstitute.org"](mailto:erosenberg@cleaninginstitute.org) ]

Derek Swick, MPP  
Senior Policy Advisor  
Regulatory and Scientific Affairs  
American Petroleum Institute  
[ [HYPERLINK "mailto:swickd@api.org"](mailto:swickd@api.org) ]

Tim A. Brown, Esq., Vice President and General Counsel  
Consumer Specialty Products Association  
[ [HYPERLINK "mailto:tbrown@cspa.org"](mailto:tbrown@cspa.org) ]

Ann M. Begley, Secretary/Co-General Counsel  
Enzyme Technical Association  
[ann.begley@morganlewis.com](mailto:ann.begley@morganlewis.com)

Dan Naatz, Vice President of Government Relations  
Independent Petroleum Association of America  
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Jim Cooper  
Vice President Petrochemicals  
American Fuel and Petrochemical Manufacturers  
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William Carteaux, President  
Society of the Plastics Industry, Inc.  
[ [HYPERLINK "mailto:wcarteaux@plasticsindustry.org"](mailto:wcarteaux@plasticsindustry.org) ]

Bill Allmond, Director  
Government Relations  
Society of Chemical Manufacturers and Affiliates Formerly the Synthetic Organic  
Chemical Manufacturers Association. (SOCMA)  
[ [HYPERLINK "mailto:allmondb@socma.com"](mailto:allmondb@socma.com) ]

Subject: Request for Assistance on Renewal of Information Collection Request: "[ SEQ CHAPTER \h \r 1]Premanufacture Review Reporting and Exemption Requirements for New Chemical Substances and Significant New Use Reporting Requirements for Chemical Substances" (EPA ICR No. 0574.18; OMB Control No. 2070-0012)

On July 25, 2018, EPA published a Notice in the Federal Register (83 Fed. Reg. 35269) titled "Agency Information Collection Activities; Proposed Renewal of Existing Collection (EPA ICR No. 0574.18); Comment Request" for the information collection request relating to [ SEQ CHAPTER \h \r 1]"Premanufacture Review Reporting and Exemption Requirements for New Chemical Substances and Significant New Use Reporting Requirements for Chemical Substances" (OMB Control No. 2070-0012) (See: [ HYPERLINK "https://www.regulations.gov/document?D=EPA-HQ-OPPT-2017-0645-0001" ].) This Notice refers to EPA's intention to request renewed Office of Management and Budget (OMB) clearance of an information collection request related to premanufacture and significant new use notice requirements for new chemicals under TSCA Section 5.

In addition to requesting public notice and comment, OMB regulations at 5 CFR 1320.8(d)(1)) require agencies to consult with potential respondents and data users about specific aspects of an information collection request (ICR) before submitting it to OMB for review and approval, regardless, in the case of ICR renewals, of whether changes have or have not been made to the collection activity.

As part of this required consultation, I am contacting you to solicit your input. Please note that if you take this opportunity to provide input, your name, affiliation, e-mail address, phone number and any information you provide (e.g., copies of e-mails) will be incorporated and attached to the ICR supporting statement, which will be a public document. In addition, the OMB Desk Examiner for the ICR in question may contact you to verify the accuracy of any comments EPA identifies in the ICR.

EPA solicits your input on the following questions:

Are the data that EPA seeks under this ICR available from any public source, or already collected by another EPA office or by another agency? If so, where can the data be found?

Is it clear what is required for data submission? If not, are there any suggestions for clarifying instructions?

Do you agree with EPA's estimated burden and costs? Are the Bureau of Labor Statistics (BLS) labor rates accurate? If you have any reason to consider the BLS labor rates as used by EPA inaccurate or inappropriate, explain your rationale.



Do you believe EPA accurately estimated the burden for the newly published document “Points to Consider When Preparing TSCA New Chemical Notifications”? Would you add any additional bases for estimating the burden from this document (i.e. additional time spent beyond review of the document)?

To access the Federal Register Notice, the ICR supporting document, and any public comments received to date, go to:

- [www.regulations.gov/](http://www.regulations.gov/)
- Enter EPA-HQ-OPPT-2017-0645-0001 in the Enter Keyword or ID field
- Click on "Search"
- Then click on any of the documents listed within the docket to read them; you likely will be most interested in the Supporting Statement, identified by its title beginning "Information Collection Request..."

Your response will be greatly appreciated. If you have any comments in response to the above questions, or with respect to any other part of the information collection, please respond by return e-mail by September 24, 2018. EPA will consider those responses, as well as any public comment received in response to the Federal Register Notice identified above, in preparing a final document for OMB review.

Thank you for your assistance.

Sincerely yours,

Adam Ross, Program Attorney  
Chemical Control Division/Office of Pollution Prevention and Toxics / Office of Chemical  
Safety and Pollution Prevention / Environmental Protection Agency  
Washington, DC 20460  
(202) 564-1625

Message

---

**From:** Ross, Adam [ross.adam@epa.gov]  
**Sent:** 7/26/2018 5:34:40 PM  
**To:** lbotelho@bc-cm.com  
**CC:** Mullings, Brandon [Mullings.Brandon@epa.gov]; Schweer, Greg [Schweer.Greg@epa.gov]  
**Subject:** ICR Supp. Statement Request - Burden Explanation  
**Attachments:** EPA-HQ-OPPT-2017-0645-SS from reg.gov.pdf

Dear Ms. Botelho:

It is a little difficult to find so attached, as we discussed over the phone, is the Supporting Statement which explains the burden for this ICR. If you have specific questions please respond to me and I may need input from the economist who prepared that section. Thanks.

Adam

Adam B. Ross  
Attorney-Advisor  
Chemical Control Division  
Office of Pollution Prevention and Toxics  
US Environmental Protection Agency  
WJC EPA East Building, Room 4419B  
1200 Pennsylvania Avenue, NW  
Washington, DC 20460  
Phone: 202-564-1625  
Fax: 202-564-9490

**From:** GlobalChem Conference [online@americanchemistry.com]  
**Sent:** 2/13/2018 8:32:53 PM  
**To:** Schweer, Greg [Schweer.Greg@epa.gov]  
**Subject:** Take a Closer Look at GlobalChem 2018!



### Take a Closer Look at GlobalChem!

Each year, the chemical industry gathers to discuss the unique challenges and opportunities they face in the regulatory arena. GlobalChem is the ideal platform for this confluence of industry professionals and government representatives. This nationally recognized Conference offers a valuable forum to review key developments in global chemicals management while looking ahead to some of the most pressing issues the industry will face.

#### A sample of GlobalChem's sessions include:

- **Lessons Learned after Year One of the New TSCA**  
This session explores the first year and a half of implementation for some of the most important changes made to TSCA. Join the discussion on how Section 5 has changed and EPA's next steps as well as learnings from the problem formulations on the initial 10 and the implications for future risk evaluations of high priority substances.
- **Global Emerging Regulations**  
As many countries consider developing or revising their chemical management regulations, a new, risk-based approach to chemical regulation is emerging as an opportunity for regulatory alignment and reducing Non-Tariff Barriers (NTBs). This session will touch on how countries are aligning their policies with the TSCA/CMP model as well as the ongoing efforts in step-wise, risk-based regulation in ASEAN and lessons learned.

[Click here](#) to view a full schedule.

---

The conference returns to Washington, DC from February 28 - March 2, 2018 and the American Chemistry Council is pleased to call the OMNI Shoreham Hotel its conference host hotel. [Click here](#) for more detailed hotel information.

#### GlobalChem Keynote



Come hear from Dr. Michael Honeycutt, Chair of EPA's Science Advisory Board, during GlobalChem's Opening Session on Thursday, March 1.

#### Optional Pre-Conference Workshop

Be sure to register for the annual workshop on TSCA & International Fundamentals, sponsored by

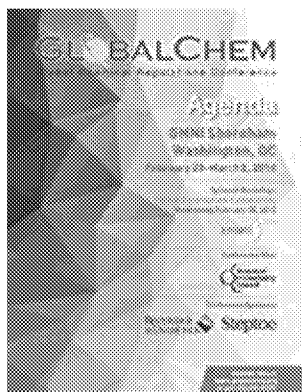


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*To unsubscribe and stop receiving future emails about the 2018 GlobalChem Conference & Exhibition, click the following link: <http://www.cvent.com/d/1vQMeYuj4UWamRFR-kEXXQ/w7hm/E1/8E?>*

## Appointment

---

**From:** Clark, Sharon [Clark.Sharon@epa.gov]  
**Sent:** 1/16/2018 3:00:49 PM  
**To:** Blunck, Christopher [Blunck.Chris@epa.gov]; Scheifele, Hans [Scheifele.Hans@epa.gov]; Schweer, Greg [Schweer.Greg@epa.gov]; Sadowsky, Don [Sadowsky.Don@epa.gov]; Williamson, Tracy [Williamson.Tracy@epa.gov]; Schechter, Kathryn [Schechter.Kathryn@epa.gov]; Doa, Maria [Doa.Maria@epa.gov]; Edelstein, Rebecca [Edelstein.Rebecca@epa.gov]; Ross, Adam [ross.adam@epa.gov]; lbergeson@lawbc.com  
**Subject:** Discuss Polymer Regulatory Flags w/ Lynn Bergeson  
**Attachments:** 00211098.pdf  
**Location:** DCRoomEast3371A/DC-EPA-EAST-OCSP-OPPT  
**Start:** 2/21/2018 6:00:00 PM  
**End:** 2/21/2018 7:00:00 PM  
**Show Time As:** Tentative

**Purpose: Polymer Regulatory Flags –  
Jan 21 is confirmed with Lynn Bergeson**

### **Meeting Location:**

US Environmental Protection Agency  
William Jefferson Clinton East Building  
1201 Constitution Avenue, NW  
Conference Room: 3371A (3<sup>rd</sup> Floor)  
Washington DC 20460

**Please bring photo identification and once through security, please have them call (202) 564-3810 for an escort to the meeting location.**

TELECONFERENCE LINE:

CONFERENCE PHONE NUMBER:  
CONFERENCE ID:

Ex. 5 Attorney Work Product (AWP)

POC:

**LYNN L. BERGESON**  
**MANAGING PARTNER**  
**BERGESON & CAMPBELL PC**  
2200 Pennsylvania Avenue, N.W. Suite 100W | Washington, D.C. 20037  
T: 202-557-3801 | F: 202-557-3836 | M: 202-257-2872 | lawbc.com  
Email: [lbergeson@lawbc.com](mailto:lbergeson@lawbc.com)

May 31, 2017

Via E-Mail

Jeffery Morris, Ph.D.  
Director  
Office of Pollution Prevention and Toxics  
Office of Chemical Safety and Pollution Prevention  
U.S. Environmental Protection Agency  
1300 Pennsylvania Avenue, N.W.  
Washington, D.C. 20004

Dear Dr. Morris:

We took note of the recent determination by the U.S. Environmental Protection Agency's (EPA) Office of Pollution Prevention and Toxics (OPPT) under Section 5(a)(3)(C) of the Toxic Substances Control Act (TSCA) concerning a premanufacture notification (PMN) polymer that evidently was intended to be manufactured in a way that met the polymer exemption at 40 C.F.R. § 723.250. The specific PMN is:

Number: P-17-0227

TSCA Section 5(a)(3) Determination: Chemical substance not likely to present an unreasonable risk (5(a)(3)(C)).

Chemical Name: Ex. 4 CBI

## Ex. 4 CBI

Polymer exemption flag: The chemical must be manufactured such that it meets the polymer exemption criteria as described under 40 C.F.R. § 723.250(e)(1), in addition to meeting the definition of polymer at 40 C.F.R. § 723.250(b).

## Ex. 5 Attorney Work Product (AWP)

Jeffery Morris, Ph.D.  
May 31, 2017  
Page 2

We also want to make available to OPPT a relevant work product that relates to the issue of using the chemical name to assist in managing new polymers. The enclosed paper

## **Ex. 5 Attorney Work Product (AWP)**

Sincerely,



Lynn L. Bergeson

### Attachment

cc: Ms. Wendy Cleland-Hamnett (w/attachment) (via e-mail)  
Nancy B. Beck, Ph.D. (w/attachment) (via e-mail)  
Mr. Ryan Jackson (w/attachment) (via e-mail)  
Mandy Gunasekara, Esquire (w/attachment) (via e-mail)  
Ms. Brittany Bolen (w/attachment) (via e-mail)  
Mr. Byron Brown (w/attachment) (via e-mail)  
Tanya H. Mottley, Ph.D. (w/attachment) (via e-mail)  
Mr. Ryan Schmit (w/attachment) (via e-mail)

## **Ex. 5 Attorney Work Product (AWP)**



## **Ex. 5 Attorney Work Product (AWP)**

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# **Ex. 5 Attorney Work Product (AWP)**

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## **Ex. 5 Attorney Work Product (AWP)**



## **Ex. 5 Attorney Work Product (AWP)**

# **Ex. 5 Attorney Work Product (AWP)**

Message

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**From:** Schweer, Greg [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=4FE412A2024B4F548EEB02E7E931F484-GSCHWEER]  
**Sent:** 4/2/2020 12:34:10 PM  
**To:** French, Lee [lee.french@dupont.com]; Castorano, Michael [michael.castorano-1@dupont.com]  
**CC:** Hundal, Amrit [Hundal.Amrit@epa.gov]; Moss, Kenneth [Moss.Kenneth@epa.gov]  
**Subject:** RE: Agreement to authorize transmittal of TSCA CBI via Outlook email with designated Agency representatives during the modified working conditions due to COVID-19  
**Attachments:** P-20-xxxx Cover Letter.pdf; P-20-xxxx DETERMINATION.pdf

Lee,

Attached are the password-protected Consent Order and Cover Letter. Contact Amrit and she will provide the password to you.

---

**From:** French, Lee <lee.french@dupont.com>  
**Sent:** Wednesday, April 01, 2020 10:06 AM  
**To:** Schweer, Greg <Schweer.Greg@epa.gov>; Castorano, Michael <michael.castorano-1@dupont.com>  
**Cc:** Hundal, Amrit <Hundal.Amrit@epa.gov>; Moss, Kenneth <Moss.Kenneth@epa.gov>  
**Subject:** RE: Agreement to authorize transmittal of TSCA CBI via Outlook email with designated Agency representatives during the modified working conditions due to COVID-19

Hi Greg,

In the interest of expediting the completion of the submission review we authorize the use of email to transmit the materials needed to finalize review process.  
Signed waiver is attached.

Regards,

**Lee French**  
PS&R TSCA Consultant  
1801 Larkin Center Dr.,  
Larkin Lab; Office 351  
Midland, MI 48642



[Lee.French@dupont.com](mailto:Lee.French@dupont.com)  
[www.dupont.com](http://www.dupont.com)

---

**From:** Schweer, Greg <Schweer.Greg@epa.gov>  
**Sent:** Tuesday, March 31, 2020 12:35 PM  
**To:** French, Lee <lee.french@dupont.com>; Castorano, Michael <michael.castorano-1@dupont.com>  
**Cc:** Hundal, Amrit <Hundal.Amrit@epa.gov>; Moss, Kenneth <Moss.Kenneth@epa.gov>  
**Subject:** [EXTERNAL] Agreement to authorize transmittal of TSCA CBI via Outlook email with designated Agency representatives during the modified working conditions due to COVID-19

Lee and Michael,

In an effort to encourage social distancing and help reduce community spread of COVID-19, most EPA staff have been authorized to telework until at least April 3, 2020. With a majority of EPA staff now teleworking from remote sites, some minor changes to the normal TSCA section 5 review processes, including the TSCA section 5(a)(3) determination processes, are required. Specifically, the normal process by which section 5(a)(3)(C) determination documents and section 5(e) orders are transmitted to submitters, because they contain information claimed as CBI, are hard copies submitted by the mail or courier services and via fax machines. These methods of delivery are not available from remote sites and therefore other means of transmitting this information must be utilized.

Given this extraordinary situation, and to avoid delay in addressing TSCA section 5 requirements, the Agency is offering an option to allowed affected persons to agree to allow EPA to transmit these materials via normal non-encrypted Outlook email. If you agree to this, the Agency will transmit these documents to you via email during the period in which a majority of EPA staff is teleworking. In the absence of this agreement, EPA may need to extend the review period for your submission or issue a unilateral order under Section 5(e).

Please note that agreeing to this process is a limited waiver of the TSCA CBI procedural protections, which generally restricts the transmission of CBI over a non-encrypted email system. That said, EPA's email system is compliant with all applicable Federal government information security provisions, including the Federal Information Security Management Act, and EPA's email systems meet the level of protection required for storing and transmitting CBI. Furthermore, your agreement will not constitute a waiver of substantive CBI protections, meaning that the information transmitted and claimed as confidential will only be disclosed consistent with TSCA, other applicable laws, and associated implementing regulations.

If you wish to grant EPA a limited waiver to transmit the materials via EPA's email system during the period in which a majority of EPA staff is teleworking, please have your authorized representative complete, sign, and return the attached to Greg Schweer ([Schweer.greg@epa.gov](mailto:Schweer.greg@epa.gov)) as well as to any EPA staff who were cc'd on the email sent to you. Also please follow the instructions below for the transmittal of information subject to this agreement. If you have any questions about this communication or the described process, please contact Greg Schweer at (202) 564-8469 or the EPA Program Manager assigned to the case.

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<https://www.dupont.com/email-disclaimer.html>

ED\_005294A\_00000720-00002

Message

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**From:** Schweer, Greg [Schweer.Greg@epa.gov]  
**Sent:** 4/1/2020 4:25:35 PM  
**To:** French, Lee [lee.french@dupont.com]; Castorano, Michael [michael.castorano-1@dupont.com]  
**CC:** Hundal, Amrit [Hundal.Amrit@epa.gov]; Moss, Kenneth [Moss.Kenneth@epa.gov]  
**Subject:** Re: Agreement to authorize transmittal of TSCA CBI via Outlook email with designated Agency representatives during the modified working conditions due to COVID-19

Thanks Lee

---

**From:** French, Lee <lee.french@dupont.com>  
**Sent:** Wednesday, April 1, 2020 10:06 AM  
**To:** Schweer, Greg <Schweer.Greg@epa.gov>; Castorano, Michael <michael.castorano-1@dupont.com>  
**Cc:** Hundal, Amrit <Hundal.Amrit@epa.gov>; Moss, Kenneth <Moss.Kenneth@epa.gov>  
**Subject:** RE: Agreement to authorize transmittal of TSCA CBI via Outlook email with designated Agency representatives during the modified working conditions due to COVID-19

Hi Greg,

In the interest of expediting the completion of the submission review we authorize the use of email to transmit the materials needed to finalize review process.  
Signed waiver is attached.

Regards,

**Lee French**  
PS&R TSCA Consultant  
1801 Larkin Center Dr.,  
Larkin Lab; Office 351  
Midland, MI 48642



Lee.French@dupont.com  
[www.dupont.com](http://www.dupont.com)

---

**From:** Schweer, Greg <Schweer.Greg@epa.gov>  
**Sent:** Tuesday, March 31, 2020 12:35 PM  
**To:** French, Lee <lee.french@dupont.com>; Castorano, Michael <michael.castorano-1@dupont.com>  
**Cc:** Hundal, Amrit <Hundal.Amrit@epa.gov>; Moss, Kenneth <Moss.Kenneth@epa.gov>  
**Subject:** [EXTERNAL] Agreement to authorize transmittal of TSCA CBI via Outlook email with designated Agency representatives during the modified working conditions due to COVID-19

Lee and Michael,

In an effort to encourage social distancing and help reduce community spread of COVID-19, most EPA staff have been authorized to telework until at least April 3, 2020. With a majority of EPA staff now teleworking from remote sites, some minor changes to the normal TSCA section 5 review processes, including the TSCA

section 5(a)(3) determination processes, are required. Specifically, the normal process by which section 5(a)(3)(C) determination documents and section 5(e) orders are transmitted to submitters, because they contain information claimed as CBI, are hard copies submitted by the mail or courier services and via fax machines. These methods of delivery are not available from remote sites and therefore other means of transmitting this information must be utilized.

Given this extraordinary situation, and to avoid delay in addressing TSCA section 5 requirements, the Agency is offering an option to allowed affected persons to agree to allow EPA to transmit these materials via normal non-encrypted Outlook email. If you agree to this, the Agency will transmit these documents to you via email during the period in which a majority of EPA staff is teleworking. In the absence of this agreement, EPA may need to extend the review period for your submission or issue a unilateral order under Section 5(e).

Please note that agreeing to this process is a limited waiver of the TSCA CBI procedural protections, which generally restricts the transmission of CBI over a non-encrypted email system. That said, EPA's email system is compliant with all applicable Federal government information security provisions, including the Federal Information Security Management Act, and EPA's email systems meet the level of protection required for storing and transmitting CBI. Furthermore, your agreement will not constitute a waiver of substantive CBI protections, meaning that the information transmitted and claimed as confidential will only be disclosed consistent with TSCA, other applicable laws, and associated implementing regulations.

If you wish to grant EPA a limited waiver to transmit the materials via EPA's email system during the period in which a majority of EPA staff is teleworking, please have your authorized representative complete, sign, and return the attached to Greg Schweer ([Schweer.greg@epa.gov](mailto:Schweer.greg@epa.gov)) as well as to any EPA staff who were cc'd on the email sent to you. Also please follow the instructions below for the transmittal of information subject to this agreement. If you have any questions about this communication or the described process, please contact Greg Schweer at (202) 564-8469 or the EPA Program Manager assigned to the case.

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Message

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**From:** Schweer, Greg [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=4FE412A2024B4F548EEB02E7E931F484-GSCHWEER]  
**Sent:** 3/31/2020 4:34:56 PM  
**To:** lee.french@dupont.com; michael.castorano-1@dupont.com  
**CC:** Hundal, Amrit [Hundal.Amrit@epa.gov]; Moss, Kenneth [Moss.Kenneth@epa.gov]  
**Subject:** Agreement to authorize transmittal of TSCA CBI via Outlook email with designated Agency representatives during the modified working conditions due to COVID-19  
**Attachments:** Authorization Form.docx

Lee and Michael,

In an effort to encourage social distancing and help reduce community spread of COVID-19, most EPA staff have been authorized to telework until at least April 3, 2020. With a majority of EPA staff now teleworking from remote sites, some minor changes to the normal TSCA section 5 review processes, including the TSCA section 5(a)(3) determination processes, are required. Specifically, the normal process by which section 5(a)(3)(C) determination documents and section 5(e) orders are transmitted to submitters, because they contain information claimed as CBI, are hard copies submitted by the mail or courier services and via fax machines. These methods of delivery are not available from remote sites and therefore other means of transmitting this information must be utilized.

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If you wish to grant EPA a limited waiver to transmit the materials via EPA's email system during the period in which a majority of EPA staff is teleworking, please have your authorized representative complete, sign, and return the attached to Greg Schweer (Schweer.greg@epa.gov) as well as to any EPA staff who were cc'd on the email sent to you. Also please follow the instructions below for the transmittal of information subject to this agreement. If you have any questions about this communication or the described process, please contact Greg Schweer at (202) 564-8469 or the EPA Program Manager assigned to the case.

**Agreement to authorize transmittal of TSCA Confidential Business Information (CBI) via Outlook email by designated Agency representatives during the period of EPA telework due to COVID-19**

Documents concerning: PMN-XX-XXX

**COMPANY** authorizes EPA to transmit documents related to the above referenced TSCA submission, including information claimed as CBI, to **COMPANY** through EPA's Outlook email system. This authorization applies only during those periods where EPA staff working on PMN-XX-XXX are teleworking due to COVID-19 concerns and may be withdrawn at any time.

I have the authority to sign this on behalf of **COMPANY**

Signature of authorized person: \_\_\_\_\_

Name of authorized person printed or typed: \_\_\_\_\_

Title: \_\_\_\_\_

Email address: \_\_\_\_\_

Telephone number: \_\_\_\_\_

**COMPANY** \_\_\_\_\_



Message

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**From:** Schweer, Greg [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=4FE412A2024B4F548EEB02E7E931F484-GSCHWEER]  
**Sent:** 3/30/2020 7:42:23 PM  
**To:** Berger, Tom C. [Berger@khlaw.com]  
**CC:** Daniels, Rhys G. [daniels@khlaw.com]; Bauer, Jeff [Bauer.Jeff@epa.gov]  
**Subject:** RE: P-16-05X3

Hi Tom.

I am not ignoring you. I did check with Jeff Bauer early last week on this case. He filled me in on the requests he had made of RAD to review submitted test data and your request for a meeting. However, believe it or not, we have been having issues reliably being able to access our CBI-secure LAN. This hampers our ability to efficiently complete work. I will check on the status of your case as soon as I can.

---

**From:** Berger, Tom C. <Berger@khlaw.com>  
**Sent:** Monday, March 30, 2020 11:51 AM  
**To:** Schweer, Greg <Schweer.Greg@epa.gov>  
**Cc:** Daniels, Rhys G. <daniels@khlaw.com>  
**Subject:** RE: P-16-05X3

Hi Greg –

Hope all is well.

Just thought I would check in with you on the Green Chemistry award winner LVEA (Lauren Davis) and P-16-05X3 (where I had hidden the integer “X”) with Jeff Bauer.

Thanks all always - Tom

---

**From:** Berger, Tom C.  
**Sent:** Tuesday, March 24, 2020 11:12 AM  
**To:** Schweer, Greg <Schweer.Greg@epa.gov>  
**Cc:** Daniels, Rhys G. <daniels@khlaw.com>  
**Subject:** RE: P-16-05X3

Greg – thanks so much as always. I also have an LVE with Lauren Davis where a Green Chemistry award winner is held up in the process. Lauren has been responsive but the case has stalled (again, however, I understand the challenges you are facing).

These are my two “priority” cases.

Tom

---

**From:** Schweer, Greg <Schweer.Greg@epa.gov>  
**Sent:** Tuesday, March 24, 2020 11:07 AM  
**To:** Berger, Tom C. <Berger@khlaw.com>  
**Cc:** Daniels, Rhys G. <daniels@khlaw.com>  
**Subject:** Re: P-16-05X3

Tom,

Yes, things are a bit crazy. I will check into the case status today or tomorrow.

Sent from my iPhone

On Mar 24, 2020, at 10:48 AM, Berger, Tom C. <[Berger@khlaw.com](mailto:Berger@khlaw.com)> wrote:

Hi Greg –

Obviously things are crazy and I don't want to push Jeff too hard but no response from Jeff on this case for a month.

Hang in there....

Tom

---

**From:** Berger, Tom C.  
**Sent:** Monday, March 23, 2020 6:22 PM  
**To:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>  
**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>  
**Subject:** RE: P-16-05X3

Hi Jeff –

Apologies – just want to make sure you are getting these emails. Understand if there are delays.

Tom

---

**From:** Berger, Tom C.  
**Sent:** Thursday, March 19, 2020 5:22 PM  
**To:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>  
**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>  
**Subject:** RE: P-16-05X3

Hi Jeff – checking in again – thanks - Tom

---

**From:** Berger, Tom C.  
**Sent:** Monday, March 16, 2020 1:40 PM  
**To:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>  
**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>  
**Subject:** RE: P-16-05X3

Hi Jeff –

I know things are crazy but checking in again – thanks - Tom

---

**From:** Berger, Tom C.  
**Sent:** Wednesday, March 11, 2020 3:43 PM  
**To:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>

**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>

**Subject:** RE: P-16-05X3

Hi Jeff –

Checking in again - thanks

---

**From:** Berger, Tom C.

**Sent:** Friday, March 6, 2020 1:33 PM

**To:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>

**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>

**Subject:** RE: P-16-05X3

Hi Jeff –

The submitter is quite anxious – can we touch base next week?

Thanks much - Tom

---

**From:** Berger, Tom C.

**Sent:** Tuesday, February 25, 2020 9:08 AM

**To:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>

**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>

**Subject:** RE: P-16-05X3

Hi Jeff –

Just checking in on this – thanks - Tom

---

**From:** Berger, Tom C.

**Sent:** Thursday, February 20, 2020 12:18 PM

**To:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>

**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>

**Subject:** RE: P-16-05X3

Hi Jeff –

I hope that all is well.

Per our discussions, the submitter has modified the questions to focus on toxicity/risk issues and submitted them via CDX yesterday. Can we start looking at conference call dates the week of March 9?

Thanks and best regards,  
Tom

Thomas C. Berger

Partner

tel: 202.434.4285 | fax: 202.434.4646 | [berger@khlaw.com](mailto:berger@khlaw.com)

1001 G Street, N.W., Suite 500 West | Washington, D.C. 20001

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**From:** Berger, Tom C.  
**Sent:** Wednesday, January 29, 2020 11:41 AM  
**To:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>  
**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>  
**Subject:** RE: P-16-05X3

Hi Jeff –

Apologies we keep playing phone tag – can we discuss how to convert the below questions into questions that would be acceptable to RAD so we can schedule a call with you and RAD? Your voicemail suggested the below are more legal/regulatory than risk-based questions. We still need the below questions answered – perhaps we tee up the more scientific ones for RAD then have the call to address both types of questions. The submitter is under growing commercial pressure.

Thanks much again - Tom

---

**From:** Berger, Tom C.  
**Sent:** Monday, January 20, 2020 3:50 PM  
**To:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>  
**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>  
**Subject:** RE: P-16-05X3

Hi Jeff –

Apologies that we could not connect last week. Let's try to touch base tomorrow (Tuesday) if possible to discuss how to move this forward.

Thanks again – Tom

Thomas C. Berger  
Partner  
tel: 202.434.4285 | fax: 202.434.4646 | [berger@khlaw.com](mailto:berger@khlaw.com)  
1001 G Street, N.W., Suite 500 West | Washington, D.C. 20001

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---

**From:** Berger, Tom C.  
**Sent:** Monday, January 13, 2020 2:50 PM  
**To:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>  
**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>  
**Subject:** RE: P-16-05X3  
**Importance:** High

Hi Jeff –

Following is the list of questions we are considering submitting through CDX. Please let me know if these look ok.

Thanks again and best regards,  
Tom

\* \* \*

*(1) Based on review of the submitted physical-chemical properties test data, does EPA now agree that use in spray applications as described in the PMN poses no unreasonable risk of injury and so plans to revoke the consent order?*

*(2) If so, what is the process for revoking the current consent order? Does the submitter now need to request that EPA revoke the order, or will EPA itself initiate revocation? What is the expected timing for revocation? How would EPA communicate such revocation?*

*(3) How would revocation of the consent order impact the final SNUR for the subject substance?*

*(4) Would a SNUN be a more expedient approach?*

\* \* \*

---

**From:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>  
**Sent:** Wednesday, January 8, 2020 8:56 AM  
**To:** Berger, Tom C. <[Berger@khlaw.com](mailto:Berger@khlaw.com)>  
**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>  
**Subject:** RE: P-16-05X3

Tom, I am expecting information from the engineer today or tomorrow on the spray test, I left you a message. There is a new procedure for us to set up meeting with RAD. I am to have the submitter send in a list of questions for RAD, they will assign someone up there as a Lead person who has two weeks and will set a date for when we can have a meeting. This may be our best route to other than just me bugging them to get things done. There were a series of emails on this case last week but now everyone is back from the holidays I am trying to get this case moving again.

Jeff Bauer - Program Manager  
United States Environmental Protection Agency (USEPA)  
Office of Pollution Prevention and Toxics (OPPT)  
New Chemicals Program (7405M)

<http://www.epa.gov/oppt/newchems/>

EPA East Building, room 4133M  
1201 Constitution Ave., NW  
Washington, DC 20004  
Phone: 202-564-9042, Fax: 202-564-9490

---

**From:** Berger, Tom C. <[Berger@khlaw.com](mailto:Berger@khlaw.com)>  
**Sent:** Tuesday, January 07, 2020 4:16 PM  
**To:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>  
**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>  
**Subject:** RE: P-16-05X3

Hi Jeff –

I hope you had a great holiday! The client was wondering if we could have a conference call on this, this week or next. Please advise.

Thanks much – Tom

Thomas C. Berger  
Partner  
tel: 202.434.4285 | fax: 202.434.4646 | [berger@khlaw.com](mailto:berger@khlaw.com)  
1001 G Street, N.W., Suite 500 West | Washington, D.C. 20001

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**From:** Berger, Tom C.  
**Sent:** Tuesday, December 10, 2019 2:10 PM  
**To:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>  
**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>  
**Subject:** RE: P-16-05X3

Hi Jeff –

Just checking back in – thanks - Tom

---

**From:** Berger, Tom C.  
**Sent:** Thursday, December 5, 2019 9:46 AM  
**To:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>  
**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>  
**Subject:** RE: P-16-05X3

Hi Jeff –

When we spoke before Thanksgiving (I hope you had a great one!) you indicated that the reports were being reviewed and that I should reach out to you in early December.

Is there any update?

Thanks much and best regards – Tom

Thomas C. Berger

Partner

tel: 202.434.4285 | fax: 202.434.4646 | [berger@khlaw.com](mailto:berger@khlaw.com)

1001 G Street, N.W., Suite 500 West | Washington, D.C. 20001

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**From:** Berger, Tom C.

**Sent:** Monday, November 18, 2019 1:17 PM

**To:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>

**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>

**Subject:** RE: P-16-05X3

Hi Jeff –

The PMN submitter asked me to reach out to you to see if we can schedule a conference call (including EPA, K&H, and the submitter) on this case re status and pathforward.

Thanks - Tom

---

**From:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>

**Sent:** Friday, March 29, 2019 5:43 PM

**To:** Berger, Tom C. <[Berger@khlaw.com](mailto:Berger@khlaw.com)>; Schweer, Greg <[Schweer.Greg@epa.gov](mailto:Schweer.Greg@epa.gov)>

**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>

**Subject:** RE: P-16-05X3

Tom,

I set the meeting up for Wednesday April 3, at 11 am. RAD has accepted the invitation for that time.

Jeff Bauer - Program Manager

United States Environmental Protection Agency (USEPA)

Office of Pollution Prevention and Toxics (OPPT)

New Chemicals Program (7405M)

<http://www.epa.gov/oppt/newchems/>

EPA East Building, room 4133M

1201 Constitution Ave., NW

Washington, DC 20004  
Phone: 202-564-9042, Fax: 202-564-9490

---

**From:** Bauer, Jeff  
**Sent:** Tuesday, March 26, 2019 11:37 AM  
**To:** 'Berger, Tom C.' <Berger@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>  
**Cc:** Daniels, Rhys G. <daniels@khlaw.com>  
**Subject:** RE: P-16-05X3

Tom, I left you a voice message, I am seeing what time it best for RAD to be part of the call.

Jeff Bauer - Program Manager  
United States Environmental Protection Agency (USEPA)  
Office of Pollution Prevention and Toxics (OPPT)  
New Chemicals Program (7405M)  
<http://www.epa.gov/oppt/newchemicals/>

EPA East Building, room 4133M  
1201 Constitution Ave., NW  
Washington, DC 20004  
Phone: 202-564-9042, Fax: 202-564-9490

---

**From:** Berger, Tom C. <Berger@khlaw.com>  
**Sent:** Tuesday, March 26, 2019 11:30 AM  
**To:** Bauer, Jeff <Bauer.Jeff@epa.gov>; Schweer, Greg <Schweer.Greg@epa.gov>  
**Cc:** Daniels, Rhys G. <daniels@khlaw.com>  
**Subject:** RE: P-16-05X3

Hi folks –

Just thought I would check in with you on this.

Thanks again - Tom

---

**From:** Berger, Tom C.  
**Sent:** Friday, March 22, 2019 2:12 PM  
**To:** 'Bauer.jeff@Epa.gov' <Bauer.jeff@Epa.gov>; 'Schweer, Greg' <Schweer.Greg@epa.gov>  
**Cc:** Daniels, Rhys G. <daniels@khlaw.com>  
**Subject:** P-16-05X3

Hi folks –

I hope you are doing well. Jeff – this is the PMN case that my colleague, Dr. Rhys Daniels, spoke with you about earlier this week.

The issue is development of data needed to amend the existing section 5(e) order for this substance to add an additional use, and EPA approval of protocols for same. Would the Agency be available for a short conference call on this on one of the following days?:

- March 27 (except 12-2 ET)



- April 2
- April 3
- April 4

This is becoming more urgent from a commercial standpoint.

Thanks much - Tom

Thomas C. Berger

Partner

tel: 202.434.4285 | fax: 202.434.4646 | [berger@khlaw.com](mailto:berger@khlaw.com)

1001 G Street, N.W., Suite 500 West | Washington, D.C. 20001

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Message

---

**From:** Schweer, Greg [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=4FE412A2024B4F548EEB02E7E931F484-GSCHWEER]  
**Sent:** 3/24/2020 3:06:59 PM  
**To:** Berger, Tom C. [Berger@khlaw.com]  
**CC:** Daniels, Rhys G. [daniels@khlaw.com]  
**Subject:** Re: P-16-05X3

Tom,

Yes, things are a bit crazy. I will check into the case status today or tomorrow.

Sent from my iPhone

On Mar 24, 2020, at 10:48 AM, Berger, Tom C. <Berger@khlaw.com> wrote:

Hi Greg –

Obviously things are crazy and I don't want to push Jeff too hard but no response from Jeff on this case for a month.

Hang in there....

Tom

---

**From:** Berger, Tom C.  
**Sent:** Monday, March 23, 2020 6:22 PM  
**To:** Bauer, Jeff <Bauer.Jeff@epa.gov>  
**Cc:** Daniels, Rhys G. <daniels@khlaw.com>  
**Subject:** RE: P-16-05X3

Hi Jeff –

Apologies – just want to make sure you are getting these emails. Understand if there are delays.

Tom

---

**From:** Berger, Tom C.  
**Sent:** Thursday, March 19, 2020 5:22 PM  
**To:** Bauer, Jeff <Bauer.Jeff@epa.gov>  
**Cc:** Daniels, Rhys G. <daniels@khlaw.com>  
**Subject:** RE: P-16-05X3

Hi Jeff – checking in again – thanks - Tom

---

**From:** Berger, Tom C.  
**Sent:** Monday, March 16, 2020 1:40 PM  
**To:** Bauer, Jeff <Bauer.Jeff@epa.gov>

**Cc:** Daniels, Rhys G. <daniels@khlaw.com>

**Subject:** RE: P-16-05X3

Hi Jeff –

I know things are crazy but checking in again – thanks - Tom

---

**From:** Berger, Tom C.

**Sent:** Wednesday, March 11, 2020 3:43 PM

**To:** Bauer, Jeff <Bauer.Jeff@epa.gov>

**Cc:** Daniels, Rhys G. <daniels@khlaw.com>

**Subject:** RE: P-16-05X3

Hi Jeff –

Checking in again - thanks

---

**From:** Berger, Tom C.

**Sent:** Friday, March 6, 2020 1:33 PM

**To:** Bauer, Jeff <Bauer.Jeff@epa.gov>

**Cc:** Daniels, Rhys G. <daniels@khlaw.com>

**Subject:** RE: P-16-05X3

Hi Jeff –

The submitter is quite anxious – can we touch base next week?

Thanks much - Tom

---

**From:** Berger, Tom C.

**Sent:** Tuesday, February 25, 2020 9:08 AM

**To:** Bauer, Jeff <Bauer.Jeff@epa.gov>

**Cc:** Daniels, Rhys G. <daniels@khlaw.com>

**Subject:** RE: P-16-05X3

Hi Jeff –

Just checking in on this – thanks - Tom

---

**From:** Berger, Tom C.

**Sent:** Thursday, February 20, 2020 12:18 PM

**To:** Bauer, Jeff <Bauer.Jeff@epa.gov>

**Cc:** Daniels, Rhys G. <daniels@khlaw.com>

**Subject:** RE: P-16-05X3

Hi Jeff –

I hope that all is well.

Per our discussions, the submitter has modified the questions to focus on toxicity/risk issues and submitted them via CDX yesterday. Can we start looking at conference call dates the week of March 9?

Thanks and best regards,  
Tom

Thomas C. Berger  
Partner  
tel: 202.434.4285 | fax: 202.434.4646 | [berger@khlaw.com](mailto:berger@khlaw.com)  
1001 G Street, N.W., Suite 500 West | Washington, D.C. 20001

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**From:** Berger, Tom C.  
**Sent:** Wednesday, January 29, 2020 11:41 AM  
**To:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>  
**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>  
**Subject:** RE: P-16-05X3

Hi Jeff –

Apologies we keep playing phone tag – can we discuss how to convert the below questions into questions that would be acceptable to RAD so we can schedule a call with you and RAD? Your voicemail suggested the below are more legal/regulatory than risk-based questions. We still need the below questions answered – perhaps we tee up the more scientific ones for RAD then have the call to address both types of questions. The submitter is under growing commercial pressure.

Thanks much again - Tom

---

**From:** Berger, Tom C.  
**Sent:** Monday, January 20, 2020 3:50 PM  
**To:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>  
**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>  
**Subject:** RE: P-16-05X3

Hi Jeff –

Apologies that we could not connect last week. Let's try to touch base tomorrow (Tuesday) if possible to discuss how to move this forward.

Thanks again – Tom

Thomas C. Berger  
Partner  
tel: 202.434.4285 | fax: 202.434.4646 | [berger@khlaw.com](mailto:berger@khlaw.com)  
1001 G Street, N.W., Suite 500 West | Washington, D.C. 20001

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---

**From:** Berger, Tom C.  
**Sent:** Monday, January 13, 2020 2:50 PM  
**To:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>  
**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>  
**Subject:** RE: P-16-05X3  
**Importance:** High

Hi Jeff –

Following is the list of questions we are considering submitting through CDX. Please let me know if these look ok.

Thanks again and best regards,  
Tom

\* \* \*

*(1) Based on review of the submitted physical-chemical properties test data, does EPA now agree that use in spray applications as described in the PMN poses no unreasonable risk of injury and so plans to revoke the consent order?*

*(2) If so, what is the process for revoking the current consent order? Does the submitter now need to request that EPA revoke the order, or will EPA itself initiate revocation? What is the expected timing for revocation? How would EPA communicate such revocation?*

*(3) How would revocation of the consent order impact the final SNUR for the subject substance?*

*(4) Would a SNUN be a more expedient approach?*

\* \* \*

---

**From:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>  
**Sent:** Wednesday, January 8, 2020 8:56 AM  
**To:** Berger, Tom C. <[Berger@khlaw.com](mailto:Berger@khlaw.com)>  
**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>  
**Subject:** RE: P-16-05X3

Tom, I am expecting information from the engineer today or tomorrow on the spray test, I left you a message. There is a new procedure for us to set up meeting with RAD. I am to have the submitter send in a list of questions for RAD, they will assign someone up there as a Lead person who has two weeks

and will set a date for when we can have a meeting. This may be our best route to other than just me bugging them to get things done. There were a series of emails on this case last week but now everyone is back from the holidays I am trying to get this case moving again.

Jeff Bauer - Program Manager  
United States Environmental Protection Agency (USEPA)  
Office of Pollution Prevention and Toxics (OPPT)  
New Chemicals Program (7405M)  
<http://www.epa.gov/oppt/newchemicals/>

EPA East Building, room 4133M  
1201 Constitution Ave., NW  
Washington, DC 20004  
Phone: 202-564-9042, Fax: 202-564-9490

---

**From:** Berger, Tom C. <[Berger@khlaw.com](mailto:Berger@khlaw.com)>  
**Sent:** Tuesday, January 07, 2020 4:16 PM  
**To:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>  
**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>  
**Subject:** RE: P-16-05X3

Hi Jeff –

I hope you had a great holiday! The client was wondering if we could have a conference call on this, this week or next. Please advise.

Thanks much – Tom

Thomas C. Berger  
Partner  
tel: 202.434.4285 | fax: 202.434.4646 | [berger@khlaw.com](mailto:berger@khlaw.com)  
1001 G Street, N.W., Suite 500 West | Washington, D.C. 20001

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**From:** Berger, Tom C.  
**Sent:** Tuesday, December 10, 2019 2:10 PM  
**To:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>  
**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>  
**Subject:** RE: P-16-05X3

Hi Jeff –

Just checking back in – thanks - Tom

---

**From:** Berger, Tom C.  
**Sent:** Thursday, December 5, 2019 9:46 AM  
**To:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>  
**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>  
**Subject:** RE: P-16-05X3

Hi Jeff –

When we spoke before Thanksgiving (I hope you had a great one!) you indicated that the reports were being reviewed and that I should reach out to you in early December.

Is there any update?

Thanks much and best regards – Tom

Thomas C. Berger  
Partner  
tel: 202.434.4285 | fax: 202.434.4646 | [berger@khlaw.com](mailto:berger@khlaw.com)  
1001 G Street, N.W., Suite 500 West | Washington, D.C. 20001

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---

**From:** Berger, Tom C.  
**Sent:** Monday, November 18, 2019 1:17 PM  
**To:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>  
**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>  
**Subject:** RE: P-16-05X3

Hi Jeff –

The PMN submitter asked me to reach out to you to see if we can schedule a conference call (including EPA, K&H, and the submitter) on this case re status and pathforward.

Thanks - Tom

---

**From:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>  
**Sent:** Friday, March 29, 2019 5:43 PM  
**To:** Berger, Tom C. <[Berger@khlaw.com](mailto:Berger@khlaw.com)>; Schweer, Greg <[Schweer.Greg@epa.gov](mailto:Schweer.Greg@epa.gov)>  
**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>  
**Subject:** RE: P-16-05X3

Tom,

I set the meeting up for Wednesday April 3, at 11 am. RAD has accepted the invitation for that time.

Jeff Bauer - Program Manager  
United States Environmental Protection Agency (USEPA)  
Office of Pollution Prevention and Toxics (OPPT)  
New Chemicals Program (7405M)  
<http://www.epa.gov/oppt/newchemicals/>

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1201 Constitution Ave., NW  
Washington, DC 20004  
Phone: 202-564-9042, Fax: 202-564-9490

---

**From:** Bauer, Jeff  
**Sent:** Tuesday, March 26, 2019 11:37 AM  
**To:** 'Berger, Tom C.' <[Berger@khlaw.com](mailto:Berger@khlaw.com)>; Schweer, Greg <[Schweer.Greg@epa.gov](mailto:Schweer.Greg@epa.gov)>  
**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>  
**Subject:** RE: P-16-05X3

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Jeff Bauer - Program Manager  
United States Environmental Protection Agency (USEPA)  
Office of Pollution Prevention and Toxics (OPPT)  
New Chemicals Program (7405M)  
<http://www.epa.gov/oppt/newchemicals/>

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Phone: 202-564-9042, Fax: 202-564-9490

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**From:** Berger, Tom C. <[Berger@khlaw.com](mailto:Berger@khlaw.com)>  
**Sent:** Tuesday, March 26, 2019 11:30 AM  
**To:** Bauer, Jeff <[Bauer.Jeff@epa.gov](mailto:Bauer.Jeff@epa.gov)>; Schweer, Greg <[Schweer.Greg@epa.gov](mailto:Schweer.Greg@epa.gov)>  
**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>  
**Subject:** RE: P-16-05X3

Hi folks –

Just thought I would check in with you on this.

Thanks again - Tom

---

**From:** Berger, Tom C.  
**Sent:** Friday, March 22, 2019 2:12 PM  
**To:** 'Bauer.jeff@Epa.gov' <[Bauer.jeff@Epa.gov](mailto:Bauer.jeff@Epa.gov)>; 'Schweer, Greg' <[Schweer.Greg@epa.gov](mailto:Schweer.Greg@epa.gov)>  
**Cc:** Daniels, Rhys G. <[daniels@khlaw.com](mailto:daniels@khlaw.com)>  
**Subject:** P-16-05X3



Hi folks –

I hope you are doing well. Jeff – this is the PMN case that my colleague, Dr. Rhys Daniels, spoke with you about earlier this week.

The issue is development of data needed to amend the existing section 5(e) order for this substance to add an additional use, and EPA approval of protocols for same. Would the Agency be available for a short conference call on this on one of the following days?:

- March 27 (except 12-2 ET)
- April 2
- April 3
- April 4

This is becoming more urgent from a commercial standpoint.

Thanks much - Tom

Thomas C. Berger

Partner

tel: 202.434.4285 | fax: 202.434.4646 | [berger@khlaw.com](mailto:berger@khlaw.com)  
1001 G Street, N.W., Suite 500 West | Washington, D.C. 20001

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Message

---

**From:** Schweer, Greg [Schweer.Greg@epa.gov]  
**Sent:** 2/12/2020 10:38:05 AM  
**To:** Berger, Tom C. [Berger@khlaw.com]  
**Subject:** Re: PMN backlog

Tom,

This is the best I can do at present. You do not need to attribute this to me.

*On our webpage titled "Statistics for the New Chemicals Review Program under TSCA" (<https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/statistics-new-chemicals-review#stats>), we provide statistics on the active cases under review. The statistics as of 2/1/2020 were posted recently and show the active number of cases down from 352 on 1/1/2020 to 303 cases on 2/1/2020. Of these 303 cases, approximately 38 cases were in the risk assessment phase, 93 cases were in the risk characterization phase, 122 cases were awaiting additional information from the submitter, 30 cases were in the regulatory decision and action development stage, and 20 cases were awaiting the submitter signature for an Order." We were able to complete a substantial number of cases in January and we continue to actively work to reduce the backlog of PMN submissions that have been under review for over 90 days.*

---

**From:** Berger, Tom C. <Berger@khlaw.com>  
**Sent:** Tuesday, February 11, 2020 9:12 PM  
**To:** Schweer, Greg <Schweer.Greg@epa.gov>  
**Subject:** Re: PMN backlog

Anything I could get by noon Wednesday would be helpful but of course understand if you can't respond.

Thanks as always - Tom

On Feb 11, 2020, at 9:57 AM, Berger, Tom C. <Berger@khlaw.com> wrote:

Hi Greg –

I hope that all is well!

During Keller and Heckman's next monthly "30/30" webinar, which is tomorrow, I will be talking about how the regulated community should not be afraid of the PMN section 5 process. I was going to mention faster reviews and reduced PMN backlog. Can you give me and very general information/stats on these topics? The last figures I have are from last October ("278 PMNs"). I will or will not give attribution for any information you provide as you indicate.

Thanks much –

Tom

Thomas C. Berger

Partner

tel: 202.434.4285 | fax: 202.434.4646 | [berger@khlaw.com](mailto:berger@khlaw.com)  
1001 G Street, N.W., Suite 500 West | Washington, D.C. 20001

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Message

---

**From:** Schweer, Greg [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=4FE412A2024B4F548EEB02E7E931F484-GSCHWEER]  
**Sent:** 3/6/2019 1:21:20 PM  
**To:** Christina Franz [Christina\_Franz@americanchemistry.com]  
**Subject:** Fwd: Global Chem Presentations for morning of March 6  
**Attachments:** 2019 Global Chem Presentation - Changes to the New Chemicals Program.Schweer.final.pptx; ATT00001.htm; 2019 Global Chem Presentation - Coordination.Edelstein.final.pptx; ATT00002.htm; 2019 Global Chem Presentation - Env Risk.Gallagher.final.pptx; ATT00003.htm; 2019 Global Chem Presentation - Fate & Exposure.Tobias.final.pptx; ATT00004.htm; 2019 Global Chem Presentation - Human Health.Salazar.final.pptx; ATT00005.htm; 2019 Global Chem Presentation - Workplace exposure & Releases.Prothero.final.pptx; ATT00006.htm

Sent from my iPhone

Begin forwarded message:

**From:** "Schweer, Greg" <Schweer.Greg@epa.gov>  
**To:** "Franz, Christina" <Christina\_Franz@americanchemistry.com>, "Blanco, Susan" <Susan\_Blanco@americanchemistry.com>, "Starr, Richard" <Richard\_Starr@americanchemistry.com>, "Brozena, Sarah" <Sarah\_Brozena@americanchemistry.com>  
**Cc:** "Pierce, Alison" <Pierce.Alison@epa.gov>, "Blair, Susanna" <Blair.Susanna@epa.gov>, "Gallagher, Jeffrey" <Gallagher.Jeffrey@epa.gov>, "Tobias, David" <Tobias.David@epa.gov>, "Prothero, Scott" <Prothero.Scott@epa.gov>, "Salazar, Keith" <Salazar.Keith@epa.gov>, "Edelstein, Rebecca" <Edelstein.Rebecca@epa.gov>, "Wormell, Lance" <Wormell.Lance@epa.gov>, "Henry, Tala" <Henry.Tala@epa.gov>  
**Subject:** Global Chem Presentations for morning of March 6

Christina et al.,

The EPA presentations are attached. David Tobias will be sending his bio pic to you in a separate email. We all look forward to seeing you on Wednesday.

Greg Schweer, Chief  
New Chemicals Management Branch (MC- 7405M)  
U.S. EPA, Office of Pollution Prevention and Toxics  
Phone: 202-564-8469  
Fax: 202-564-9490



# **Review of New Chemical Substances under TSCA (as amended by LCSA)**

Greg Schweer  
New Chemicals Management Branch  
Office of Pollution Prevention and Toxics

Global Chem Conference  
PMN Workshop  
March 6, 2019



## Overview

- Background on Types of Notifications
- Types of Section 5 Determinations and Outcomes
- Discussion of "Conditions of Use"
- Overview of EPA New Chemical Review Process



## **PMN, SNUN (Significant New Use Notice) and MCAN (Microbial Commercial Activity Notice) Notifications**

- Mandated by section 5 of the Toxic Substances Control Act (TSCA), EPA's New Chemicals program helps manage the potential risk to human health and the environment from chemicals new to the marketplace.
- Section 5 of TSCA requires anyone who plans to manufacture (including import) a new chemical substance for a non-exempt commercial purpose or for a significant new use (designated by EPA) to provide EPA with notice before initiating the activity.



## Exemptions from PMNs & MCANs

- **Exemption Application Not Required for:**
  - R&D Chemicals
  - Exempted Polymers of Low Concern (only annual reporting)
- **Submission of Exemption Application Required:**
  - Low Volume ( $\leq 10,000$  Kg/Yr) - 30 Day Review
  - Low Release/Exposure (LOREX) - 30 Day Review
  - Test Market Exemption (TME) - 45 Day Review
  - TSCA Experimental Release Application – 60 Day Review
  - Tier I and Tier 2 Biotechnology Exemptions
- For all exemption applications, EPA assesses whether the manufacture, processing, distribution in commerce, use or disposal of the substance will present an unreasonable risk to human health or the environment.

4

TSCA included two statutory exemptions from PMN notification: research and development (R&D) chemicals and Test Market Exemptions. EPA has developed fairly strict regulations limiting the applicability of these two exemptions.

TSCA also gave the authority to EPA to exempt manufacturers from some requirements but only if EPA determines that the intended activities associated with a substance will not present an unreasonable risk to human health or the environment. EPA has developed eligibility for four types of such exemptions: polymers of low concern, substances manufactured at low volumes (less than or equal to 10,000 kg/yr), substances that have low releases and exposures, and certain products of biotechnology that utilize only pre-approved species of microorganisms and meet strict containment and control technologies.

READ 3rd BULLET

Exemption applications are processed in less than 90 days.

These substances cannot be entered onto the TSCA Inventory.

Submitter is legally bound to conditions of manufacture, uses, exposure and engineering controls and releases to the environment.



## Types of Determinations for PMNs, SNUNs and MCANs

### **Presents an Unreasonable Risk**

- Section 5(f) order: Restriction/prohibition of manufacturing, processing, or distribution
- Section 6(a) Proposed Rule: Restriction/prohibition of manufacturing, processing, distribution, or disposal

### **Not Likely to present an unreasonable risk**

- Commercialization can commence after the determination is made
- Section 5(g) – Statement in the FR

### **Information is insufficient to permit a reasoned evaluation of the risk**

- Section 5(e) – regulation pending more information
- Section 5(e) order

### **Insufficient information to permit a reasoned evaluation and **may present** unreasonable risk**

- Section 5(e) – regulation pending more information
- Section 5(e) order



## Regulatory Options for Exemption Applications

- **Grant**
  - An exemption is granted if the chemical substance meets the eligibility requirements for the exemption.
  - Specific conditions/controls detailed in the application must be maintained throughout the duration of the exemption.
- **Deny**
  - The chemical substance does not meet the eligibility requirements for the exemption.

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In addition to PMNs, EPA has received over 15,000 exemption applications for new chemical substances since 1979. Strict criteria must be met for a substance to be eligible for these exemptions. All exemption applications are reviewed by EPA and only those for which the Agency determines that the substance will not present an unreasonable risk to human health or the environment are granted. If granted, specific conditions/controls detailed in the application must be maintained throughout the duration of the exemption including: the use(s) specified in the application; site of manufacture; exposure and release controls; and, for certain exemptions, a limit on the production volume. In addition, the exemption holder must notify processors and industrial users: 1) that the LVE substance can only be used for uses specified, and 2) of any exposure and environmental release controls identified in the notice. LVE substances are not added to the TSCA Inventory; only the holder of an LVE can manufacture the substance. EPA believes that these binding provisions of the exemption are an effective substitute for regulation under §5(e) of the TSCA.

For exemption application, EPA will deny the exemption application if EPA cannot make a finding that the manufacture, processing, distribution in commerce, use, and disposal of a new chemical substance will not present an unreasonable risk to health or the environment.



## Conditions of Use

- Conditions of use is defined as “the circumstances as determined by the Administrator, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used or disposed of.”
  - Intended conditions of use - In general, EPA considers these to be those identified in the section 5(a) notification.
  - Known conditions of use – generally includes activities within the United States that result from manufacture that is exempt from PMN submission requirements.
  - Reasonably foreseen conditions of use - are future circumstances, distinct from known or intended conditions of use, under which the Administrator expects the chemical substance to be manufactured, processed, distributed, used, or disposed of.



## Reasonably Foreseen Conditions of Use – EPA Considerations

- Reasonably foreseen conditions of use – are future circumstances, distinct from known or intended conditions of use, under which the Administrator expects the chemical substance to be manufactured, processed, distributed, used, or disposed of.
  - The identification of “reasonably foreseen” conditions of use will necessarily be a case-by-case determination and will be highly fact-specific.
  - Reasonably foreseen conditions of use will not be based on hypotheticals or conjecture.
  - EPA uses the information on the chemical substance, including information provided by the submitter, information in the literature, attributes of the chemical substance (e.g., physical-chemical properties).



## Reasonably Foreseen Conditions of Use – EPA Considerations

- Reasonably foreseen conditions of use - are future circumstances, distinct from known or intended conditions of use, under which the Administrator expects the chemical substance to be manufactured, processed, distributed, used, or disposed of.
  - EPA also uses information on analogue(s) for the chemical substance, including available data, information in the literature, attributes of the analogue (e.g., physical-chemical properties) and any difference in these attributes from the subject chemical substance.
  - The sources EPA uses to identify reasonably foreseen conditions of use include searches of internal confidential EPA PMN databases (containing use information on analogue chemicals), other U.S. government public sources, the National Library of Medicine's Hazardous Substances Data Bank (HSDB), the Chemical Abstract Service STN Platform, REACH Dossiers, technical encyclopedias (e.g., Kirk-Othmer and Ullmann), and Internet searches.



## Reasonably Foreseen Conditions of Use – EPA Considerations

- EPA applies its professional judgment, experience, and discretion when considering such factors as:
  - evidence of current use of the new chemical substance outside the United States;
  - evidence that the PMN substance is sufficiently likely to be used for the same purposes as existing chemical substances that are structurally analogous to the new chemical substance; and
  - conditions of use identified in an initial PMN submission that the submitter omits in a revised PMN.
- EPA's identification of conditions of use includes the expectation of compliance with federal and state laws, such as worker protection standards or disposal restrictions, unless case-specific facts indicate otherwise.



## Section 5 Review and Determination

- Determination: “Presents an unreasonable risk”
  - the relevant chemical substance or significant new use presents an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by the Administrator under the conditions of use. TSCA §5(a)(3)(A)
- Outcome: the Administrator shall take the actions required under section 5(f)
  - Regulation under section 5(f) – Protection Against Unreasonable Risks
    - Section 5(f) order or section 6(a) proposed rule
    - Restriction or prohibition of chemical substance

## Section 5 Review and Determination

- Determination: "May present an unreasonable risk"
  - In the absence of sufficient information to permit the Administrator to make a reasoned evaluation of the health and environmental effects of the chemical substance, the manufacture, processing, distribution in commerce, use, or disposal of such substance, or any combination of such activities, may present an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by the Administrator. TSCA §5(a)(3)(B)(i)(I).
- Outcome: the Administrator shall take the actions required under section 5(e)
  - Regulation under section 5(e) – Regulation Pending the Development of Information
    - Section 5(e) order - Typically a consent order
    - Commercialization with restrictions
    - Testing, if required, is generally due at a specified point after commercialization of the chemical substance, unless risks cannot be mitigated then testing needed before commercialization of the chemical substance





## Section 5 Review and Determination

- Determination: “Chemical substances produced in substantial quantities...” (i.e., the “exposure-based” finding)
  - Such substance is or will be produced in substantial quantities, and such substance either enters or may reasonably be anticipated to enter the environment in substantial quantities or there is or may be significant or substantial human exposure to the substance. TSCA §5(a)(3)(B)(ii)(II).
- Outcome: the Administrator shall take the actions required under section 5(e)
  - Regulation under section 5(e) – Regulation Pending the Development of Information
    - Section 5(e) order - Typically a consent order
    - Commercialization without restrictions
    - Testing generally due at a specified point after commercialization of the chemical substance



## Section 5 Review and Determination

- Determination: "Insufficient information available to permit a reasoned evaluation"
  - The information available to the Administrator is insufficient to permit a reasoned evaluation of the health and environmental effects of the relevant chemical substance or significant new use. TSCA §5(a)(3)(B)(i).
- Outcome: the Administrator shall take the actions required under section 5(e)
  - Regulation under section 5(e) – Regulation Pending the Development of Information
    - Section 5(e) order - Typically a consent order
    - Testing generally required before commercialization of the chemical substance can occur



## Section 5 Review and Determination

- Determination: “Not Likely to Present an Unreasonable Risk”
  - The relevant chemical substance or significant new use is not likely to present an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by the Administrator under the conditions of use. TSCA §5(a)(3)(C).
- Outcome: the submitter may commence manufacture of the chemical substance or manufacture or processing for a significant new use
  - Section 5(g) – Statement on Administrator Finding
    - Commercialization of the chemical substance can commence after a “not likely to present” determination is made, notwithstanding any remaining portion of the review period



## **Information Required to Be Submitted by a Manufacturer**

- Chemical Identity
- By-products and impurities
- Estimated production/import volume
- Proposed uses and amounts for each use
- Human exposure information
- Disposal methods and estimates of releases to the environment
- Existing test data in notifier's possession or control concerning human and environmental effects



## Overview of EPA Assessments

- TSCA requires new chemical manufacturers to submit only studies or data in their possession or control (*i.e.*, no minimum set of toxicity or fate studies are required)
- Because no test data are required to be submitted with a notification, predictive models/technical tools and professional judgement are used by EPA to assess potential risks
- Evaluation of risks from new chemical substances are considered throughout their product life-cycle
- EPA focuses on exposure to workers, site-specific assessment of environmental and general population exposure, and consumer exposure



# **How Best to Coordinate with EPA Throughout the Submission Process**

Rebecca Edelstein  
New Chemicals Management Branch  
PMN Prenotice and Exemptions Management Team Leader  
Office of Pollution Prevention and Toxics

Global Chem Conference  
PMN Workshop  
March 6, 2019



## Overview of Presentation

- This presentation will focus on how submitters can coordinate with EPA to make the review process more efficient.
- Pre-notice communication and consultation process
- Post-notice communication
- Contacts

Note: This presentation is primarily extracted from EPA's Points to Consider document:  
[https://www.epa.gov/sites/production/files/2018-06/documents/points\\_to\\_consider\\_document\\_2018-06-19\\_resp\\_to\\_omb.pdf](https://www.epa.gov/sites/production/files/2018-06/documents/points_to_consider_document_2018-06-19_resp_to_omb.pdf)



## Pre-notice Topics

- Consolidation requests
- Whether and what type of new chemical notice is needed
  - Questions about jurisdiction, definitions, whether a chemical substance qualifies for an exemption
- Questions and discussion of issues related to the manufacture, processing, or use of a specific new chemical substance
  - Toxicity data, data gaps, modeling, exposure
  - Analogues
  - What to submit





## What to Expect from Pre-notice Consultation

- Request a pre-notice consultation:
  - if you have questions about the review process
  - if you would like to discuss the information that should be provided in your submission
- Not intended to obtain EPA decisions on the content and likely outcome from the New Chemical Review process
  - EPA will not make a determination on whether there may or may not be potential risks to human health and/or environmental receptors
  - EPA will not make a risk management finding (e.g., not likely, may present, or will present)
- We encourage submitters to review the Points to Consider document prior to submitting a pre-notice consultation request.



## **Types of Pre-notice Communication**

- Inquiries submitted through EPA's website or by email
- Phone call to a pre-notice coordinator/EPA staff
- Teleconference
- In-person meeting

# How to Contact EPA for Pre-notice

- Email or call a pre-notice coordinator (note: do not email CBI)
- Through EPA's website: <https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/filing-pre-manufacture-notice-epa>

## Reviewing New Chemicals under the Toxic Substances Control Act (TSCA)

CONTACT US  
SHARE    

Reviewing New Chemicals  
under the Toxic  
Substances Control Act  
(TSCA) Home

Basic Information

EPA's Review Process

Filing a Premanufacture  
Notice with EPA

Regulatory Actions Under  
TSCA section 5

Premanufacture Notice  
Status

## Program Contacts and Mailing/Courier Information

**Schedule a Pre-Submission Meeting**

Staff Directory

Mailing/Courier Information

### Schedule a Pre-Submission Meeting

Please **DO NOT INCLUDE CONFIDENTIAL BUSINESS INFORMATION** in the meeting request.

#### Contact:

Greg Schweer, 202/564-8469  
Rebecca Edelstein, 202/564-1667

Name

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# How to Contact EPA for Pre-notice (cont.)

- Contact Us button on EPA website:

## Reviewing New Chemicals under the Toxic Substances Control Act (TSCA)

Reviewing New Chemicals under the Toxic Substances Control Act (TSCA) Home

Basic Information

EPA's Review Process

Filing a Premanufacture Notice with EPA

Regulatory Actions Under TSCA section 5

Premanufacture Notice Status

## Reviewing New Chemicals under TSCA Contact Us

Find program contacts and mailing/contact information

Mailing Address:

U.S. EPA  
Office of Pollution Prevention & Toxicity  
1200 Pennsylvania Avenue, NW  
Mail Code 7425-M  
Washington, DC 20460



Report a Violation

More pages

Violations at environmental law and regulations

Please use the form below to send us comments or questions. Be sure to include your e-mail address if you'd like a response.

Name

Please enter a name to which you'd like

E-mail

Please enter a valid e-mail address.

Comments (Required)

Please enter your comments.

Submit

- EPA can now receive pre-notice communications through CDX

[illegible]



## How to Submit Through CDX

- Similar to submitting a PMN through CDX:
  1. Click on the 'Primary Authorized Official' link next to 'CSPP: Submissions for Chemical Safety and Pesticide Programs'
  2. Select 'TSCA Section 5 Notices and Supports – ePMN' from the drop down list and click the OK button
  3. Click on the Forms link
  4. Scroll to the bottom of the screen and select 'Pre- Notice Communication' from the Form Type list
  5. Click 'Start new form'
  6. Follow the directions to create a passphrase and the new submission.
- Please notify staff at EPA by phone or email that you have submitted a Pre-notice Communication through CDX.



## Information to Include in a Pre-notice Request

- Specific identity of the chemical substance
- Type of submission (*e.g.*, PMN, SNUN, or type of exemption)
- Description of proposed and reasonably foreseeable uses
- Issues or questions the submitter wishes to raise for EPA's consideration
- Summary of any previous discussions or relevant submissions
- Whether an in-person meeting, teleconference, or written response is requested
- For a meeting request, preferred dates and times for the meeting



## **Tips to Consider in New Chemical Submission**

- Ensure that the phone numbers and email addresses provided for the technical contact and authorized official are correct.
- Do not underestimate your maximum 12-month production volume estimate.
- Ensure that attachments to submissions accurately reflect CBI claims made in the PMN form
  - Don't forget to redact use, company name, etc., if claimed CBI
  - Don't over-redact





## Post-PMN Submission Communication

- If risks are identified in the risk assessment, the program manager works with the submitter to identify and understand the associated exposure pathways.
- Program manager serves as the submitter's main point-of-contact with EPA
  - Program manager can be requested to set up conference calls/meetings with EPA staff
  - Program manager can be requested to provide redacted EPA assessment reports (e.g., engineering, exposure, human health and environmental hazard and risk)
- Effective communication between the program manager and submitter is essential to the PMN review process.
- As part of Lean activities in the New Chemicals Program, EPA is assigning program managers earlier in the process.



## Post-PMN Submission Communication Tips

- It is good practice to inform your EPA program manager (e-mail or phone message) that you have electronically submitted an amendment or document via CDX or that you have sent a document via fax.
- When a suspension of more than 15 days appears to be needed, we encourage you to submit a written request for suspension thru CDX for the longer time period.
- Become familiar with the TSCA Section 5(e) Consent Order boilerplate on EPA's website (<https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/new-chemicals-program-boilerplates>).

# PMN Status

- <https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/status-pre-manufacture-notices>

Cases Reviewed under Amended TSCA

Cases Reviewed Prior to June 22, 2018

## Cases Reviewed under Amended TSCA

### Instructions

By using the links to the tables below, you can search the status of your TSCA section 5 notice or exemption, by case type, by case number, status, final determination, or date (example 7/8/2016). You can enter all or part of a case number or a status entry in the search box using the following structure, e.g., **P-16-0420**, **L-16-0479**, **invalid** or **just the number 0001**. To list all entries for a certain fiscal year, you may enter P-[FY] or L-[FY] (e.g., P-16 or L-16 for 2016 cases of that type). This search will return the case status and dates for all PMNs, exemption notices, or SNURs pertaining to that fiscal year. The status page listing for a specific notice will contain the PMN, SNUR, MCAN, TERA, or exemption number, the Focus Meeting date, the interim status of the notice after the Focus meeting, the final determination of the notice, and the effective date and, if there is a SNUR on the chemical substance, the SNUR effective date. Note that final determinations where Consent Orders are the outcome are not entered into the results column until both EPA and the PMN submitter have signed the Consent Order.

Note: Cases are posted to this page after the Focus meeting; cases that have been received by EPA, but have not yet gone to Focus are not included in this list.

- [Search the Premanufacture Notices \(PMNs\) and Significant New Use Notices \(SNURs\) Table](#)
- [Search the Microbial Commercial Activity Notices \(MCANs\) Table](#)
- [Search the table with exemption decisions for low volume \(LV\), low environmental release and low human exposure \(LoREX\), or test marketing \(TMEA\) exemption applications or modification notices.](#)



## Contact Information and Links

- <https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/filing-pre-manufacture-notice-epa>
- Staff Directory tab at <https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/forms/program-contacts-and>

Rebecca Edelstein: [Edelstein.Rebecca@epa.gov](mailto:Edelstein.Rebecca@epa.gov); 202-564-1667



## **Environmental Risk Assessment: Points to Consider (PtC)**

Jeffrey S. Gallagher  
Environmental Toxicologist  
Risk Assessment Division  
Office of Pollution Prevention and Toxics

Global Chem  
Conference  
March 6, 2019



## Overview of Presentation

- Environmental Risk Assessment: Overview
- Environmental Hazard Assessment
  - Purpose
  - Approach (test data >> analogues > modelling)
- Environmental Risk Assessment
  - Risk from acute aquatic exposure
  - Risk from chronic aquatic exposure
  - Risk from soil/sediment exposure
- EPA Recommends the Submitters Consider

Note: This presentation is primarily extracted from EPA's Points to Consider document: [https://www.epa.gov/sites/production/files/2018-06/documents/points\\_to\\_consider\\_document\\_2018-06-19\\_resp\\_to\\_omb.pdf](https://www.epa.gov/sites/production/files/2018-06/documents/points_to_consider_document_2018-06-19_resp_to_omb.pdf) <sup>2</sup>



## Environmental Risk Assessment: Overview

$$\text{Hazard} \times \text{Exposure} = \text{Risk}$$

- Hazard Assessment
  - Identify adverse effects and determine concentrations at which these effects occur (concentration-response)
- Exposure Assessment
  - Calculate the concentration of the chemical in the environment (potential environmental concentrations [PEC])
- Risk Characterization
  - Compare hazard to exposure

## Environmental Hazard Assessment: Purpose

- Identify potential aquatic hazard concerns, using the following acute and chronic toxicity endpoint values ( $LC_{50}$ ,  $EC_{50}$ , ChV) to identify concern levels:

|         | Low Concern     | Moderate Concern   | High Concern |
|---------|-----------------|--------------------|--------------|
| Acute   | $\geq 100$ mg/L | 1 to $< 100$ mg/L  | $< 1$ mg/L   |
| Chronic | $\geq 10$ mg/L  | 0.1 to $< 10$ mg/L | $< 0.1$ mg/L |

- Identify the environmental hazard score (low = 1, moderate = 2, or high = 3)
  - An environmental hazard score  $>1$  will initiate the engineering and exposure assessments.
- Derive acute and chronic concentrations of concern (COC)
  - Harm to the aquatic environment may occur if the COC is exceeded